

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

**Jessica R. DesNoyer, et al.****Serial No.:** 10/750,312**Filed:** 12/30/2003**For:** STENT MANDREL SUPPORT AND  
METHOD FOR COATING STENTS**Group Art Unit:** 1792**Examiner:** Lamb, Brenda A.**CONFIRMATION NO:** 1694**Mail Stop Appeal Brief-Patents**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**AMENDED APPEAL BRIEF**

Dear Sir:

On March 12, 2008 Applicants timely appealed to the Board of Patent Appeals & Interferences (the “Board”) from the Final Rejection of Claims 1, 4-9, 11, 13, 14, and 19-25, which have been twice rejected. The following is Applicants’ Appeal Brief submitted under 37 C.F.R. § 41.37.

This “Amended” Appeal Brief is submitted in response to a 5/12/08 Notice of Non-Compliant Appeal Brief, which indicated that Applicants’ brief did not comply with 37 CFR § 41.37(c)(1)(v) (“Summary of Claimed Subject Matter”). Applicants understand that the notice of non-compliant appeal brief was triggered by a recent change in Board requirements for claims described under Section 41.37(c)(1)(v). Applicants would also like to thank Patent Appeal Center Specialist Hinton for her assistance with Applicants’ response to 5/12/08 notice by explaining the new requirement as set forth in an internal office memorandum.

**REAL PARTY IN INTEREST**

The real party in interest with regard to this appeal is Abbott Cardiovascular Systems, Inc., with its primary place of business at 3200 Lakeside Drive, Santa Clara, California 95054. Abbott Cardiovascular purchased the vascular device division and all relevant intellectual property including the instant application, of Advanced Cardiovascular Systems, also known as Guidant Corporation, in April 2006. The original assignment to Advanced Cardiovascular Systems was recorded at Reel/Frame 015350 / 0532 on May 20, 2004.

**RELATED APPEALS AND INTERFERENCES**

There are no appeals or interferences related to or that might have any bearing, direct or indirect, on the Board's decision in this appeal.

**STATUS OF CLAIMS**

Claims 1-15 and 18-26 are pending.

Claims 16, 17 were canceled.

Claims 2, 3, 10, 12, 15, 18 and 26 stand withdrawn.

Applicants are appealing to the Board the rejections of Claims 1, 4-9, 11, 13, 14, and 19-25, of which Claims 1, 9, 19, 20, 23 and 24 are independent claims.

**STATUS OF AMENDMENTS**

There were no claim amendments presented in Applicants' Feb. 12, 2008 Request for Reconsideration, which was filed in response to the Dec. 12, 2007 Final Office Action.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Applicants invention is directed, at least in part to seeking a cure for the problem of how to spray the abluminal and side surfaces of a stent, but not the luminal surface, while minimizing contact with the stent during coating. On the one hand, there is a desire for not placing the stent in contact with the mandrel surfaces. On the other hand, if there are no mandrel surfaces to shield the luminal surfaces during spraying, then the coating substance will reach the luminal surfaces.

*See Applicants' Specification at pg. 3, line 4 through pg. 4, line 5 (provided as **Exhibit A**). The solution to this problem was found in the design of a mandrel. See *Id.* at pg. 5, lines 3-9.*

FIGS. 4-10 (**Exhibit A**) depict examples of mandrels suited for preventing coating substance from reaching a stent luminal surface while minimizing the contact points. FIGS. 3A-3B (**Exhibit A**) depict an example of a mandrel assembly having a mandrel 24 according to one or more of the embodiments described in FIGS. 4-10.

**Independent Claim 1 is directed to a stent and a mandrel supporting the stent, the stent comprising a plurality of struts. The support includes a first member to contact a first end of the stent, a second member to contact a second end of the stent, and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent.** Examples of this claimed subject matter include the stent 10 shown in FIG. 1 and described on page 1, line 21 through page 2, line 2; and the stent 10 and support 20 shown in FIG. 2 and described on pages 9, line 19 through page 10, line 2. The support 20 includes a first member (coning end portion 42), a second member (coning end portion 36) and a third member (mandrel 24). Examples of the first and second members are also provided on page 11, line 3, through page 12, line 4. Claim 1 also recites that the third member (mandrel 24) is **shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the stent during application of a coating substance to the stent.** Examples of a third member having this feature include the body 50A of the stent mandrel 24 shown in FIGS. 4A-4C and described on page 13, line 1, through page 14, line 8, and the body 50B of the stent mandrel 24 shown in FIGS. 5A-5C and described on page 17, line 10, through page 18, line 12.

**Dependant Claim 4 depends from Claim 1 and describes embodiments in which the third member has a plurality of spikes. An example of a third member according to Claim 4 is shown in FIGS. 5A-5C (body 50B of mandrel 24 having spikes formed by portions 56C, 56D and 56E).** Claim 6, dependant from Claim 4, recites that the spikes do not touch the luminal surface of the stent. *See page 17, lines 20-22.*

**Independent Claim 9 is directed to a stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. The mandrel includes a member to penetrate at least partially into a longitudinal bore of the stent during the**

**application of a coating substance to the stent.** Examples of this claimed subject matter include the stent 10 shown in FIG. 1 and described on page 1, line 21 through page 2, line 2; and the stent 10 and support 20 shown in FIG. 2 and described on pages 9, line 19 through page 10, line 2. The support 20 includes a mandrel 24, which is shown in FIG. 2 and described at page 9, line 19 through page 10, line 16. Claim 9 also recites that the member **includes outward projecting walls, the length of at least one of the walls being not less than 25% of the length of the stent.** Examples of a member having this feature include the body 50B of the stent mandrel 24 shown in FIGS. 5A-5C and described on page 17, line 10, through page 18, line 12.

Independent Claim 19 is directed to **a stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. The mandrel includes a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent.** Examples of this claimed subject matter include the stent 10 shown in FIG. 1 and described on page 1, line 21 through page 2, line 2; and the stent 10 and support 20 shown in FIG. 2 and described on pages 9, line 19 through page 10, line 2. The support 20 includes a mandrel 24, which is shown in FIG. 2 and described at page 9, line 19 through page 10, line 16. Claim 19 also recites that the member includes **6 non-parallel sides.** Examples of a member having this feature include the body 50B of the stent mandrel 24 shown in FIGS. 5A-5C and described on page 17, line 10, through page 18, line 12.

Independent Claim 20 is directed to **a stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, and a mandrel.** Examples of this claimed subject matter include the stent 10 shown in FIG. 1 and described on page 1, line 21 through page 2, line 2; and the stent 10 and support 20 shown in FIG. 2 and described on pages 9, line 19 through page 10, line 2. The support 20 includes a mandrel 24, which is shown in FIG. 2 and described at page 9, line 19 through page 10, line 16. Claim 20 also recites that the member includes **a core section having at least three sides and a wall extending from each of the sides in an outwardly direction.** Examples of a member having this feature include the body 50B of the stent mandrel 24 shown in FIGS. 5A-5C and described on page 17, line 10, through page 18, line 12.

Independent Claim 23 is directed to **a stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. The mandrel includes a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent.** Examples of this claimed subject matter include the stent 10 shown in FIG. 1 and described on page 1, line 21 through page 2, line 2; and the stent 10 and support 20 shown in FIG. 2 and described on pages 9, line 19 through page 10, line 2. The support 20 includes a mandrel 24, which is shown in FIG. 2 and described at page 9, line 19 through page 10, line 16. Claim 23 also recites that the member includes **outwardly projecting walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle.** Examples of a member having this feature include the body 50B of the stent mandrel 24 shown in FIGS. 5A-5C and described on page 17, line 10, through page 18, line 12.

Independent Claim 24 is directed to **a stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. The mandrel includes a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent.** Examples of this claimed subject matter include the stent 10 shown in FIG. 1 and described on page 1, line 21 through page 2, line 2; and the stent 10 and support 20 shown in FIG. 2 and described on pages 9, line 19 through page 10, line 2. The support 20 includes a mandrel 24, which is shown in FIG. 2 and described at page 9, line 19 through page 10, line 16. Claim 24 also recites that the member includes **a first end and a second end and at least 3 sides extending between the first and second end, the length of each side being at least 25% of the length of the stent.** Examples of a member having this feature include the body 50B of the stent mandrel 24 shown in FIGS. 5A-5C and described on page 17, line 10, through page 18, line 12.

The complete claim set is provided in the **Claims Appendix.**

## **GROUNDΣ OF REJECTION TO BE REVIEWED ON APPEAL**

The issue(s) presented in this appeal is/are:

Whether Claims 1 and 4-8 are obvious under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 4,846,791 to Hattler et al. (hereinafter “*Hattler*”) in view of U.S. Pat. No. 5,674,208 to Berg et al. (“*Berg*”).

Whether Claims 1 and 4-8 are obvious under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of U.S. Pat. No. 5,389,106 to Tower (“*Tower*”).

Whether Claims 9, 11, 13-14 and 19-25 are obvious under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of U.S. Pat. No. 4,762,128 to Rosenbluth (“*Rosenbluth*”) and prior art allegedly admitted by Applicants.

## ARGUMENT

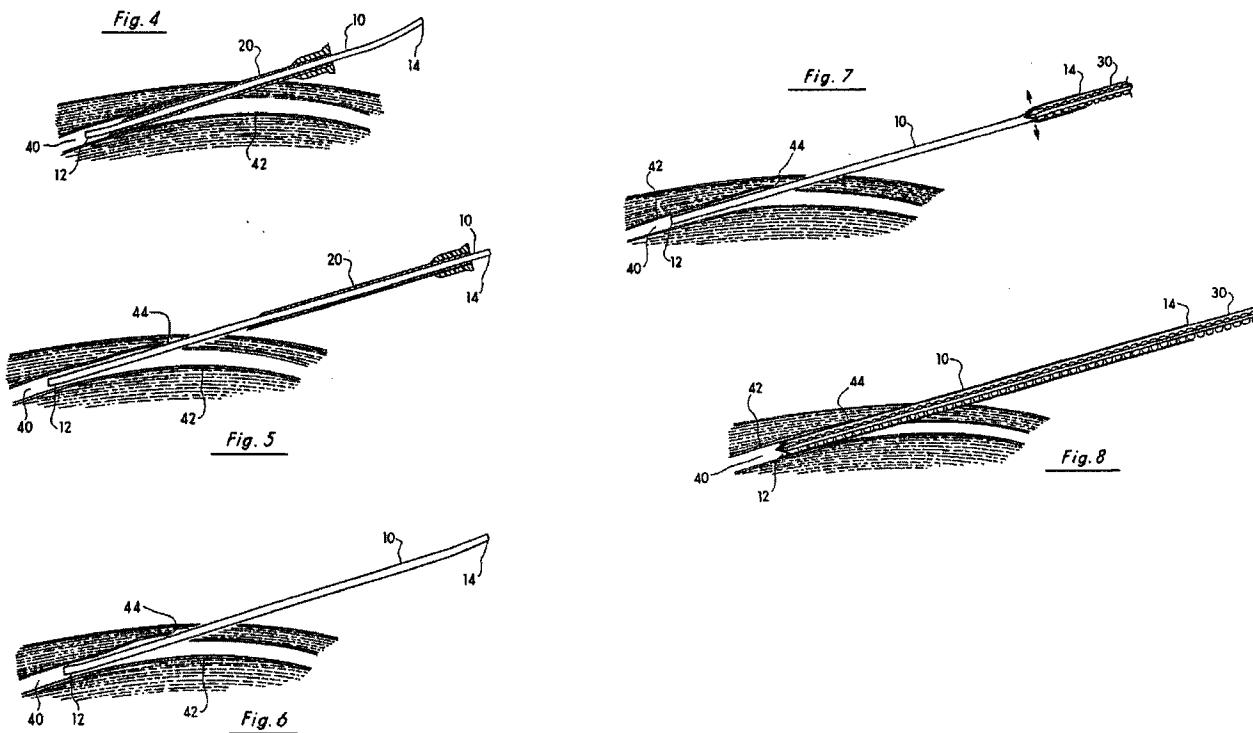
### **I. The rejection of Claims 9, 11, 13-14 and 19-25 under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of *Rosenbluth* and prior art allegedly admitted by Applicants**

The Office’s rejections of Applicants’ claims are based, in large part, on the disclosure in *Hattler*. This reference discloses a multi-lumen catheter consisting of a flexible tube and divider. The divider is inserted into the tube after the tube is inserted into a patient’s blood vessel. As best understood, the Examiner concluded that any type of stent (including scaffolding-type stents) could be used in place of *Hattler*’s tube. Also, the Examiner appears to have concluded that in view of *Rosenbluth*’s inflation catheter one of ordinary skill would have recognized that *Hattler*’s divider structure has an established function as a mandrel support for any type of stent. The relevant features of *Hattler* are discussed before addressing the merits of the rejections. A copy of *Hattler* is provided as **Exhibit B**.

#### **A. Hattler’s Multi-Lumen Catheter**

*Hattler* is directed to a multi-lumen catheter suited for delivering several medications to a patient using a single, embedded catheter tube having multiple lumens. *Hattler*’s catheter consists of a flexible tube 10 and divider piece 30 inserted into the tube 10 after the tube has been inserted into a blood vessel. *See* col. 2, ll. 15-30.

FIGS. 4-8 (reproduced below) depict, step-by-step, how the multi-lumen catheter is assembled. First, a flexible tube 10 is inserted into a hollow needle 20. Then the needle 20 is used to deliver the tube 10 to the blood vessel. Next, the needle 20 is removed so that one end 14 of the tube is outside the patient and the other end 12 is within the patient. Next the divider piece 30 is introduced to form the multiple lumens within the tube.



FIGS. 4-8 of *Hattler*  
(needle 20 inserts flex tube 10 into blood vessel 42; needle 20 is removed; then divider 30 is inserted into tube 10)

According to *Hattler*, during the steps depicted in FIGS. 7-8 a divider 30 is

inserted into the catheter tube from the distal end 14 of the tube, as shown in FIG. 7, thereby dividing the tube into a plurality of separate lumens. . . . As the divider is inserted into the tube, each of the outer edges or corners 32 of the divider contact the inside surface of the tube to form a fluid-tight seal extending the length of the divider between adjacent lumens.

Col. 4, ll. 45-60 (emphasis added). Thus, in this embodiment the divider 30 forms fluid tight seals when inserted into the tube 10. Referring to FIG. 3, these seals are formed by the tips 32 of the triangular divider 30 pressed into the walls of the tube 10. According to *Hattler* FIG. 3 depicts a multi-lumen catheter with four separate, fluid-tight lumens (shown is three separate

spaces between the sides 34 of the divider 30 and inner walls of the tube 10, and a fourth lumen formed by the area 36 within the divider). In all other embodiments of *Hattler* the divider 30 is shaped to provide multiple types of lumens all of which are designed to form a fluid tight seal between walls of divider 30 and inner wall of the tube 10. *See e.g.* col. 6, ll. 60-63 (forming grooves to insure a better seal); and FIGS. 11-17.

*Hattler* requires fluid-tight seals between the tube 10 and the divider 30 because the only conceivable purpose of *Hattler* is “catheters having multiple fluid carrying passageways.” Col. 1, ll. 6-8. In the background section it becomes evident why this is the case. *Hattler* insists upon fluid-tight seals because he is concerned with finding a replacement for multiple catheters for delivery of fluids into and out of the body. Col. 1, ll. 18-24. Multiple lumens “allows a number of different medications to be administered to the patient at one time using the same catheter.” *Id.* According to *Hattler*, the solution to the problems in the prior art is to have a divider that is “separately inserted into the catheter tube after the tube has been introduced into the blood vessel, thereby providing multiple lumens for the catheter.” Col. 2, ll. 15-23.

#### B. Independent Claims 9, 19, 20, 23 and 24

The Office’s basis for rejecting Claim 9 (as well as the other claims subject to the same rejection) appears to be little more than a conclusory statement that this claim would have been obvious in view of the disclosure in *Hattler*, Applicants’ disclosure of stent structures, and *Rosenbluth*’s disclosure of the concept of coating a stent while it is mounted on a balloon catheter. However, the Office does not carry its burden by merely describing what is in the various cited references. A *prima facie* case of obviousness can only be made if the Office first undertakes a *Graham* analysis, which requires making specific factual findings; then provides an explicit reason why, based on the *Graham* findings, Claim 9 would have been obvious at the time of the invention. *See KSR Int’l v. Teleflex*, 127 S. Ct. 1727, 1740-41 (2007); MPEP § 2143. The Final Office Action does not articulate what (if any) findings were made as to the scope of the prior art or the level of ordinary skill. Nor does the Final Office Action articulate an explicit reason why, in light of at least these *Graham* findings, Claim 9 would have been obvious. Instead, the Official Action simply states that it would have been obvious to modify the art in order to arrive at Claim 9. This is an improper basis for rejecting Applicants’ claims under Section 103.

For at least this reason Applicants respectfully ask that the Board reverse the Examiner's findings for Claim 9 because the Office appears to have failed to base its conclusions of obviousness on the *Graham* factors as required, *KSR Int'l*, 127 S. Ct. at 1734, and also failed to provide an explicit reason as to why one of ordinary skill in the art would have found it obvious to practice Claim 9 based on these *Graham* factors, as also required. *Id.* at 1740-41.

\* \* \*

Even assuming the Office undertook a proper *Graham* analysis, for at least the following two reasons no combination of the cited prior art provides a valid basis for concluding that Claim 9 would have been obvious under 35 U.S.C. § 103(a) at the time of the invention. First, the combined prior art would have rendered *Hattler* inoperable and/or *Hattler* would have taught-away from Claim 9. Second, the only explanation, on record, for making the alleged combination of the prior art at the time of the invention would have been that described in Applicants' specification, i.e., the solution to the problem of coating the underside of a stent while making minimum contact with the stent, as discussed above. Accordingly, there could not have been a *prima facie* case of obviousness because the combination of prior art is forbidden based on being tainted by hindsight.

As noted above, Claim 9 is directed to a stent and a mandrel supporting the stent. The claim includes the feature of a stent that has a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts and the mandrel includes a member including outward projecting walls. According to the Final Office Action (**Exhibit C**), and as confirmed in the Advisory Action of 3/6/08 (**Exhibit D**), Claim 9 stands rejected because the Examiner found that *Hattler*, in combination with other prior art, would have rendered Claim 9 obvious.

*Hattler* describes a multi-lumen catheter. As defined by *Hattler*, col. 1, ll. 5-24 and col. 2, ll. 1530, a multi-lumen catheter delivers different therapeutic substances to the body intravenously. Accordingly, in order for it to work, a multi-lumen catheter must have fluid-tight passageways. The passageways in *Hattler*'s catheter are formed by inserting a divider structure into a flexible tube (see FIG. 1, above). Notably, *Hattler* mentions, or at least implies at several locations the need for forming "fluid-tight" seals between the divider and tube walls, *see e.g.* col. 2, ll. 15-30, col. 4, ll. 52-64; and col. 6 ll. 53-65, obviously because the catheter, in order to

function properly, must be capable of providing fluid-tight passageways. Thus, if the seals or tube walls are not fluid tight, the catheter cannot function properly. *See e.g.*, the use configuration in FIG. 8 of *Hattler*.

Claim 9, in contrast to the prior art, is directed to a stent and a mandrel supporting the stent. The stent includes the feature of abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. Thus, a fluid freely passes in and out of the space between the stent walls and the walls of the mandrel according to the apparatus of Claim 9. If *Hattler*'s catheter were modified by replacing the tube with the stent described in Claim 9, this catheter would no longer function properly. That is, the catheter would be rendered inoperable.

"[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR Int'l Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 1740 (2007). "There is no suggestion to combine, however, if a reference teaches away from its combination with another source." *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2D (BNA) 1130, 1131 (Fed. Cir. 1994). "If when combined, the references 'would produce a seemingly inoperative device,' then they teach away from their combination". *Tec Air*, 192 F.3d at 1360; *see also In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. (BNA) 1125, 1127 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose).

Thus, a claim could not have been obvious if the combined prior art would have rendered the prior art inoperable. Under any reading of *Hattler*, the multi-lumen catheter would have been rendered inoperable if the tube 10 was replaced with a stent having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. And there would have been no other purpose for the divider in *Hattler* then to create fluid-tight passageways. Accordingly, for at least this reason Applicants ask that the Board reverse the

Examiner's finding that Claim 9 would have been obvious under 35 U.S.C. § 103(a) in view of *Hattler, Rosenbluth* and the prior art allegedly admitted by the Applicants.

A question of obviousness "must be determined in light of all the facts, and there is no rule that a single reference that teaches away will mandate a finding of non-obviousness". *Medichem v. Rolabo*, 437 F.3d 1157, (Fed. Cir. 2006). Even assuming, however, that the teaching-away deficiencies in *Hattler* are not dispositive of the obviousness question, the Board should alternatively reverse the Examiner's rejection of Claim 9 because there is no rationale for the alleged combination in the record, other than to provide a solution to a problem that was identified by the Applicants (the Examiner fails to cite any prior art demonstrating that the problem identified by Applicants was known in the prior art).

As noted above, the Examiner never provided a reason for the alleged combination, although this is required under the law. *See KSR Int'l*, 127 S. Ct. at 1740-41. Applicants can only speculate, therefore, that the reason derived either from a motivating purpose that lead to Applicants' conception, i.e., the problem identified and solved by Applicants, which is improper, or some motivation implicit in the art of record. However, upon review of the art of record, Applicants conclude that there is nothing in the art that would have suggested or motivated one of ordinary skill (whether for Applicants' purpose or some other purpose) to modify *Hattler* in the manner suggested.

As explained above, Applicants sought to cure the problem of how to spray the abluminal and side surfaces of a stent, but not the luminal surface. The solution to the problem was found in the design of the mandrel. As such Claim 9 describes a member including the feature of "outwardly projecting walls". The prior art of record, however, provides no alternative motivation or rationale. *Hattler* obviously provides no motivation for the alleged combination. As to *Rosenbluth*, this reference shows a stent mounted on a balloon catheter. *See FIGS. 1-8* (provided as **Exhibit E**). A stent is mounted on a balloon catheter according to *Rosenbluth* so that it can be delivered to a site in the body. But there is no rationale provided in this reference that would explain why one of ordinary skill would have used *Hattler*'s divider to mount a stent or would have replaced a balloon catheter with a divider.

As best understood, the Examiner found that one of ordinary skill would have been motivated in view of *Rosenbluth* to mount a stent on anything capable of functioning as a

mandrel. *See e.g.*, Advisory Action of 3/6/08 (provided as **Exhibit D**). Applicants assume, therefore, the Examiner concluded that Claim 9 would have been obvious because the claim is nothing more than a mere substitution of known elements to yield predictable results. *See MPEP § 2143*. The Examiner's analysis (assuming Applicants' understanding is correct), however, is fundamentally flawed because it never provides a reason why one of ordinary skill would have known or concluded that the divider 30 has an established function of supporting a stent. The divider 30 is inserted into a flexible tube. Its function is to form fluid-tight passageways while allowing the assembled catheter to be adequately flexible to conform to the natural curvature of a blood vessel. *See FIG. 8 of Hattler*. One of ordinary skill would have concluded, therefore, that a tube 10 as described by *Hattler* is clearly not the same thing as a stent. Thus, *Hattler*'s divider 30 would not have had an established function of supporting a stent according to one of ordinary skill in the art. ***Indeed, Hattler's divider 30 has an established function of supporting a stent to the same extent that a pencil has an established function of supporting a stent.*** While both may be capable of supporting a stent, it can hardly be said that stent-supporting is an "established function" of either of these structures.

There being no established function to support a stent, a rationale of "combining known elements to yield predictable results", MPEP § 2143, does not apply here. Therefore, no basis exists to reject Claim 9 under 35 U.S.C. § 103(a). For this additional reason Applicants also ask that the Board reverse the rejection of Claim 9 under 35 U.S.C. § 103(a).

For similar reasons as those given for Claim 9, Applicants also ask that the Board reverse the Examiner's rejection of independent Claims 19, 20, 23 and 24 under Section 103.

#### C. Dependant Claims 11, 13, 14, 21, 22 and 25

Claims 11, 13, 14, 21, 22 and 25 depend from Claims 9, 20 and 24, respectively, and recite additional features that further distinguish Applicants' invention over the art of record. However, it is not necessary to point out the additional features recited in these dependant claims. Because Claims 11, 13, 14, 21, 22 and 25 depend from allowable claims, they are also allowable. For this reason, Applicants ask that all standing the rejections of Claims 11, 13, 14, 21, 22 and 25 under 35 U.S.C. § 103 be withdrawn.

**II. The rejection of Claims 1 and 4-8 under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of *Berg*****A. Claim 1**

The Examiner rejected Claim 1 in part because *Hattler* is believed to have suggested that tube 10 may be replaced with the claimed scaffolding-type stent. Applicants contend, however, that this rejection under Section 103 is improper because *Hattler* specifically teaches away from replacing the flexible tube 10 with a scaffolding-type stent. Applicants also traverse this rejection because the rejection relies on the incorrect view that *Hattler*'s meaning for a catheter is not limited to flexible tubes, rather, it covers any stent having a plurality of struts, including scaffolding-type stents ("stents") covered by Claim 1.

According to *Hattler* the tube 10 is made from flexible, expandable material such as amber latex, vinyl or silicon rubber. According to *Hattler* the tube 10 has little, if any radial stiffness. This highly flexible tube is evident from the disclosure, and also important to the operation of the catheter, for the following reasons: (1) the divider 30 actually needs supports 38 to prevent the walls of the tube 10 from collapsing when inserted into a blood vessel, *see* col. 5, ll. 25-44; (2) the tube 10 "must also have sufficient flexibility to allow it to follow the natural curvature of . . . [a] blood vessel", col. 4, ll. 27-29 of *Id* (emphasis added); and (3) a fluid-tight seal is formed by making the divider 30 outer dimensions larger-than the tube's inner wall diameter (so that the tube is radially expanded in order to extend the divider into the blood vessel), *see* col. 4, ll. 61-64 (from this one of ordinary skill would have concluded that the tube 10 must have very little hoop, radial or bending stiffness in order for a divider 30 to have dimensions larger than the dimensions of the tube 10 to be inserted into the tube after the tube has been inserted into a curved blood vessel). Thus, for these reasons one of ordinary skill would have found that pursuing the course of replacing a flexible tube with a scaffolding stent counterproductive in view of *Hattler*. Accordingly, *Hattler* teaches-away from replacing the tube 10 with a scaffolding stent because a scaffolding stent fails to provide any of the features outlined above; instead, a scaffolding stent would preclude such features. Claim 1 would therefore have not have been obvious over *Hattler* in combination with *Berg*. For this reason Applicants ask that the Board reverse the Examiner's rejection of Claim 1 in view of *Hattler* and *Berg*.

As Applicants clearly set forth in the specification, the stent in Claim 1 is one that provides radial stiffness to serve as scaffolding. *See* pg. 1 of **Exhibit A**. As just explained, such a structure would frustrate the requirements of the tube 10 in *Hattler*. Moreover, the Examiner has never explained or cited to evidence supporting the view that one of ordinary skill would have concluded that a tube as depicted in FIG. 8 is synonymous or equivalent to a stent that functions as scaffolding. These are entirely different devices. Indeed, Applicants have never even heard of a scaffolding-type stent that would be capable of being used in the manner depicted in FIG. 8.

As noted above, the Examiner's rejection relies on the premise that one of ordinary skill would have concluded that the meaning of catheter in *Hattler* includes a scaffolding type stent, which Applicants have demonstrated is clearly not the case. Therefore, the rejection of Claim 1 under 35 U.S.C. § 103(a) in view of *Hattler* and *Berg* cannot stand. For this reason Applicants ask that the Board reverse the Examiner's rejection of Claim 1.

#### B. Claim 4

Claim 4 recites a stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts, and wherein the third member has a plurality of spikes.

The Examiner rejected Claim 4 in part because *Hattler* is believed to have suggested that tube 10 may be replaced with the claimed scaffolding-type stent. Applicants contend, however, that this rejection under Section 103 is improper because *Hattler* specifically teaches away from replacing the flexible tube 10 with a scaffolding-type stent. Applicants also traverse this rejection because the rejection relies on the incorrect view that *Hattler*'s meaning for a catheter is not limited to flexible tubes, rather, it covers any stent having a plurality of struts, including scaffolding-type stents ("stents") covered by Claim 4.

For the same reasons as those set forth above for Claim 1, Applicants request that the Board reverse the rejection of Claim 4 because *Hattler* teaches-away from replacing the tube 10 with a stent as claimed in Claim 4. Applicants also request that the Board reverse the Examiner's findings because the rejection relies on the premise that one of ordinary skill would have concluded that the meaning of catheter in *Hattler* includes a scaffolding type stent, which Applicants have demonstrated is not the case. Therefore, the rejection of Claim 4 under 35 U.S.C. § 103(a) in view of *Hattler* and *Berg* cannot stand.

### C. Claim 6

Claim 6 depends from 4 and recites “wherein the plurality of spikes do not contact the luminal surface of the stent”. This claim stands rejected as obvious over *Hattler* et al because it is believed that *Hattler* discloses an embodiment in which protrusions do not contact the tube. Applicants assume this statement is made in reference to the disclosure under col. 5, ll. 25-44 of *Hattler*.

The Examiner’s analysis is flawed. The reference passage in *Hattler* is actually referring to the situation in which the ends of the divider are such that there is sufficient support for the tube 10 (therefore, the protrusions are not needed). One example of such a divider structure would be that shown in FIG. 16. In these cases, the divider 30, due to its structure forms 6 passages and also adequately supports the walls of the flexible tube to prevent it from collapsing. Moreover, as should be apparent from the above discussion, *Hattler* would not function properly if the ends of the divider 30 did not touch the inner walls of the tube because a fluid-tight seal is needed.

Applicants submit that the Examiner has not made out a *prima facie* case of obviousness, either because the feature of “wherein the plurality of spikes do not contact the luminal surface of the stent” would have rendered *Hattler* inoperable or because the combined art does not teach every feature of the claim. For these reasons Applicants request that the Board reverse the rejection of Claim 6 under 35 U.S.C. § 103(a) in view of *Hattler* and *Berg*.

### D. Dependant Claims 5, 7 and 8

Claims 5, 7 and 8 depend from Claim 1 and recite additional features that further distinguish Applicants’ invention over the art of record. However, it is not necessary to point out the additional features recited in these dependant claims. Because Claims 5, 7 and 8 depend from allowable claims, they are also allowable. For this reason, Applicants ask that the standing rejections of Claims 5, 7 and 8 under 35 U.S.C. § 103, respectively, be withdrawn.

**III. The rejection of Claims 1 and 4-8 under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of *Tower***

**A. Claim 1**

For the same reasons as that given above under Section II.A Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**B. Claim 4**

For the same reasons as that given above under Section II.B Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**C. Claim 6**

For the same reasons as that given above under Section II.C Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**D. Defendant Claims 5, 7 and 8**

For the same reasons as that given above under Section II.D Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**CONCLUSION**

The Examiner has failed, as a matter of law, to set forth a case of obviousness under 35 U.S.C. § 103(a). Applicants therefore respectfully request that the Board reverse the rejections of the claims and order the application to be passed to issue.

Respectfully submitted,

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## **CLAIMS APPENDIX**

**WHAT IS CLAIMED:**

1. (previously presented) A stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts, the support comprising:
  - a first member to contact a first end of the stent;
  - a second member to contact a second end of the stent; and
  - a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the stent during application of a coating substance to the stent.
2. (withdrawn) The stent and support of claim 1, wherein the third member is cylindrical in shape.
3. (withdrawn) The stent and support of claim 2, wherein the outer diameter of the third member is about 1.35 mm to about 1.4 mm less than the inner diameter of the stent as positioned on the support.
4. (previously presented) The stent and support of claim 1, wherein the third member has a plurality of spikes.
5. (previously presented) The stent and support of claim 4, wherein the plurality of spikes contact the luminal surface of the stent.
6. (previously presented) The stent and support of claim 4, wherein the plurality of spikes do not contact the luminal surface of the stent.

7. (previously presented) The stent and support of claim 1, wherein the cross section of the third member is star shaped.
8. (previously presented) The stent and support of claim 1, wherein the cross section of the third member is “+” or “X” shaped.
9. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including outward projecting walls, the length of at least one of the walls being not less than 25% of the length of the stent.
10. (withdrawn) The stent and mandrel of claim 9, wherein a cross section of at least one of the walls is rectangular in shape.
11. (previously presented) The stent and mandrel of claim 9, wherein a cross section of at least one of the walls is triangular in shape.
12. (withdrawn) The stent and mandrel of claim 9, wherein at least one of the walls has a radius of curvature.
13. (previously presented) The stent and mandrel of claim 9, wherein the length of the wall is not less than 50% of the length of the stent.

14. (previously presented) The stent and mandrel of claim 9, wherein the length of the wall is equal to or greater than the length of the stent.

15. (withdrawn) A mandrel to support a stent during the application of a coating composition to the stent, comprising a mandrel body capable of being inserted at least partially into a longitudinal bore of a stent and a spiral wall circumscribing the mandrel body.

16-17. (canceled)

18. (withdrawn) A mandrel to support a stent during application of a coating substance to the stent, comprising: a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance, the member including 3 outward projecting walls, each wall including a pair of opposing parallel sides.

19. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including 6 non-parallel sides.

20. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a core section having at least three sides and a wall extending from each of the sides in an outwardly direction.

21. (previously presented) The stent and mandrel of Claim 20, wherein the walls are triangular in cross section, are square in cross section or have a curved shape.

22. (previously presented) The stent and mandrel of Claim 20, wherein the cross section of the core has a shape of a square, triangle, or rectangle.

23. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including outwardly projecting walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle.

24. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including a first end and a second end and at least 3 sides extending between the first and second end, the length of each side being at least 25% of the length of the stent.

25. (previously presented) The stent and mandrel of claim 24, wherein the length of each side is equal to or greater than the length of the stent.

26. (withdrawn) A method of coating a stent with a substance, comprising:  
supporting a stent on a stent mandrel support of claims 1 – 15 and 18-25; and  
applying a coating composition to the stent.

## **EVIDENCE APPENDIX**

Attached hereto are the following:

**Exhibit A:** Substitute Specification for U.S. Patent Application Serial No.: 10/750,312 (filed in response to 9/1/2005 Official Action)

**Exhibit B:** U.S. Pat. No. 4,846,791 to ("Hattler").

**Exhibit C:** U.S. pat. No. 4,762,128 to ("Rosenbluth").

**Exhibit D:** Final Office Action mailed December 12, 2007.

**Exhibit E:** Advisory Action mailed march 6, 2008.

# **RELATED PROCEEDINGS**

# **APPENDIX**

There are no related proceedings.

# EXHIBIT A

# EXHIBIT B

# EXHIBIT C

# EXHIBIT D

# EXHIBIT E

# EXHIBIT A

**STENT MANDREL Fixture SUPPORT AND METHOD FOR  
COATING STENTS**

5

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Technical Field

This invention relates to stent mandrel fixtures or supports used during the  
10 process of coating stents.

Background

Blood vessel occlusions are commonly treated by mechanically enhancing blood  
flow in the affected vessels, such as by employing a stent. Stents act as scaffoldings,  
15 functioning to physically hold open and, if desired, to expand the wall of affected vessels.  
Typically stents are capable of being compressed, so that they can be inserted through  
small lumens via catheters, and then expanded to a larger diameter once they are at the  
desired location. Examples in the patent literature disclosing stents include U.S. Patent  
No. 4,733,665 issued to Palmaz, U.S. Patent No. 4,800,882 issued to Gianturco, and U.S.  
20 Patent No. 4,886,062 issued to Wiktor.

FIG. 1 illustrates a conventional stent 10 formed from a plurality of struts 12. The  
plurality of struts 12 are radially expandable and interconnected by connecting elements  
14 that are disposed between the adjacent struts 12, leaving lateral openings or gaps 16  
between the adjacent struts 12. The struts 12 and the connecting elements 14 define a

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tubular stent body having an outer, tissue-contacting (abluminal) surface and an inner (luminal) surface.

Stents are used not only for mechanical intervention but also as vehicles for providing biological pharmacological therapy. Biological Pharmacological therapy can

5 be achieved by medicating the stents. Medicated stents provide for the local administration of a therapeutic substance at the diseased site. Local delivery of a therapeutic substance is a preferred method of treatment because the substance is concentrated at a specific site and thus smaller total levels of medication can be administered in comparison to systemic dosages that often produce adverse or even toxic 10 side effects for the patient.

One method of medicating a stent 10 involves the use of a polymeric carrier coated onto the surface of the stent 10. A composition including a solvent, a polymer dissolved in the solvent, and a therapeutic substance dispersed in the blend is applied to the stent 10 by immersing the stent 10 in the composition or by spraying the composition 15 onto the stent 10. The solvent is allowed to evaporate, leaving on the surfaces a coating of the polymer and the therapeutic substance impregnated in the polymer.

The dipping or spraying of the composition onto the stent can result in a complete coverage of all stent surfaces, i.e., both luminal and abluminal surfaces, with a coating. However, from a therapeutic standpoint, drugs need only be released from the abluminal 20 stent surface, and possibly the sidewalls. Moreover, having a coating on the luminal surface of the stent can have a detrimental impact on the stent's deliverability as well as the coating's mechanical integrity. A polymeric coating can increase the coefficient of friction between the stent and the delivery balloon. Additionally, some polymers have a

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“sticky” or “tacky” consistency. If the polymeric material either increases the coefficient of friction or ~~adherers~~adheres to the catheter balloon, the effective release of the stent from the balloon after deflation can be compromised. Adhesive, polymeric stent coatings can also experience extensive balloon sheer damage post-deployment, which could result

5 in a thrombogenic luminal stent surface. Accordingly, there is a need to eliminate or minimize the amount of coating that is applied to the inner surface of the stent. Reducing or eliminating the polymer from the stent luminal surface also means a reduction in total polymer load, which is a desirable goal for optimizing long-term biocompatibility of the device.

10 A method for preventing the composition from being applied to the inner surface of the stent is by placing the stent over a mandrel that fittingly mates within the inner diameter of the stent. A tubing can be inserted within the stent such that the outer surface of the tubing is in contact with the inner surface of the stent. A tubular mandrel that makes contact with the inner surface of the stent can cause coating defects. A high degree of surface contact between the stent and the supporting apparatus can provide regions in which the liquid composition can flow, wick, and collect as the composition is applied to the stent. As the solvent evaporates, the excess composition hardens to form excess coating at and around the contact points between the stent and the supporting apparatus. Upon removal of the coated stent from the supporting apparatus, the excess coating may stick to the apparatus, thereby removing some of the coating from the stent and leaving bare areas. Alternatively, the excess coating may stick to the stent, thereby leaving excess coating composition as clumps or pools on the struts or webbing between the struts.

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Accordingly, there is a tradeoff when the inner surface of the stent is masked in that coating defects such as pools and clumps can be formed on the stent. There is a need for eliminating or at least minimizing the coating that is formed on the inner surface of the stent as well as coating defects that are formed on the stent struts or between the stent struts caused by the high degree of surface contact between the stent and the mandrel. A mandrel design is ~~need~~needed that addresses these concerns.

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SUMMARY

A stent mandrel ~~fixture support~~ to support a stent during application of a coating substance to the stent is provided, comprising a first member to contact a first end of the stent; a second member to contact a second end of the stent; and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the stent.

A mandrel to support a stent during application of a coating substance to a stent is provided, comprising a member to penetrate at least partially into a longitudinal bore of a stent during the application of a coating substance, the member including outward projecting walls, the length of at least one of the walls being not less than 25% of the length of the stent.

A mandrel to support a stent during the application of a coating composition to the stent is provided, comprising a mandrel body capable of being inserted at least partially into a longitudinal bore of a stent and a spiral wall circumscribing the mandrel body.

A mandrel to support a stent during the application of a coating composition to the stent is provided, comprising a mandrel body capable of being inserted at least partially into a longitudinal bore of a stent, wherein the mandrel body or a segment thereof is defined by a shape selected from the group consisting of configuration 2, 3, 4, 5, 6 or 7 -- as defined in the ~~detail~~detailed description.

A mandrel to support a stent during application of a coating substance to a stent is provided comprising a member to penetrate at least partially into a longitudinal bore of a

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stent during the application of a coating substance, the member including 3 pairs of opposing parallel sides.

A mandrel to support a stent during application of a coating substance to a stent is provided comprising a member to penetrate at least partially into a longitudinal bore of a stent during the application of a coating substance, the member including 6 non-parallel sides.

A mandrel to support a stent during application of a coating substance to a stent is provided comprising a core section having at least three sides and a wall extending from each of the sides in an outwardly direction.

A mandrel to support a stent during application of a coating substance to a stent is provided comprising a member to penetrate at least partially into a longitudinal bore of a stent during the application of a coating substance, the member including outward projecting walls disposed around the circumference of the mandrel, wherein the wall converge with their neighboring walls at an angle.

A method is also provided to coat a stent using the embodiments of the mandrel of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the present invention are described with reference to the following figures, wherein like reference numerals refer to like parts throughout the various views unless otherwise specified.

5 FIG. 1 illustrates a conventional stent;

FIG. 2 illustrates a stent mandrel ~~fixture-support~~ in accordance with an embodiment of the invention;

FIG. 3A illustrates a disassembled view of the stent mandrel ~~fixture-support~~ of FIG. 2;

10 FIG. 3B illustrates a stent mandrel ~~fixture-support~~ in accordance with another embodiment of the invention;

FIG. 4A, FIG. 4B, and FIG. 4C illustrate a cross section, perspective view, and top view, respectively, of a stent mandrel;

15 FIG. 5A, FIG. 5B, FIG. 5C, and FIG. 5D illustrate a cross section, perspective view, top view, and a preassembled view, respectively, of a stent mandrel according to another embodiment of the invention;

FIG. 6A, FIG. 6B, and FIG. 6C illustrate a cross section, perspective view, and top view, respectively, of a stent mandrel according to another embodiment of the invention;

20 FIG. 7A, FIG. 7B, FIG. 7C, and FIG. 7D illustrate a cross section, perspective view, top view, and preassembled view, respectively, of a stent mandrel according to another embodiment of the invention;

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FIG. 8A, FIG. 8B, and FIG. 8C illustrate a cross section, perspective view, and top view, respectively, of a stent mandrel according to another embodiment of the invention;

FIG. 9A, FIG. 9B, and FIG. 9C illustrate a cross section, perspective view, and 5 top view, respectively, of a stent mandrel according to another embodiment of the invention;

FIG. 10A, FIG. 10B, and FIG. 10C illustrate a cross section, perspective view, and top view, respectively, of a stent mandrel according to another embodiment of the invention; and

10 FIG. 11A, FIG. 11B and FIG. 11C illustrate the resulting luminal surface coating of stents after a conducted experiment using a conventional stent mandrel fixture support, a stent mandrel fixture support with a mandrel diameter of 0.061 inches, and a stent mandrel fixture support with a mandrel diameter of 0.0625 inches, respectively.

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DETAILED DESCRIPTION

The following description is provided to enable any person having ordinary skill in the art to make and use the invention, and is provided in the context of a particular application and its requirements. Various modifications to the embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the invention. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles, features and teachings disclosed herein.

The embodiment of the invention minimize the surface contact between the stent and the mandrel ~~fixture support~~ so as to reduce or prevent coating defect on the stent. It is believed that the embodiments of the invention can also prevent a coating from being formed on the inner surface of the stent or reduce the amount of coating that is formed on the inner surface of the stent. This reduces the total polymer load on the stent 10, thereby improving long-term biocompatibility and ensuring that most of the coating is on the abluminal surface where it provides the most benefit. Further, problematic interactions between a delivery mechanism (e.g., delivery balloon) and the stent luminal surface are eradicated, thereby increasing the ease of stent deliverability.

FIG. 2 illustrates a stent mandrel ~~fixture support~~ 20 in accordance with an embodiment of the invention. The ~~fixture support~~ 20 for supporting a stent 10 is illustrated to include a support member 22, a mandrel 24, and a lock member 26. The support member 22 can connect to a motor 30A so as to provide rotational motion about the longitudinal axis of the stent 10, as depicted by arrow 32, during a coating process.

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Another motor 30B can also be provided for moving the support member 22 in a linear direction, back and forth, along a rail 34.

FIG. 3A illustrates a disassembled view of the stent mandrel fixture-support 20.

The support member 22 includes a coning end portion 36, tapering inwardly at an angle

5  $\phi_1$  of about 15° to about 75°, more narrowly from about 30° to about 60°. By way of example, angle  $\phi_1$  can be about 45°. The coning end portion 36 supports the stent 10 at one end during a coating process. In accordance with one embodiment of the invention, the mandrel 24 can be permanently affixed to the coning end portion 36. Alternatively, the support member 22 can include a bore 38 for receiving a first end 40 of the mandrel  
10 24. The first end 40 of the mandrel 24 can be threaded to screw into a bore 38 or, alternatively, can be retained within the bore 38 by a friction fit. The bore 38 should be deep enough so as to allow the mandrel 24 to securely mate with the support member 22. The depth of the bore 38 can also be over-extended so as to allow a significant length of the mandrel 24 to penetrate or screw into the bore 38. The bore 38 can also extend  
15 completely through the support member 22. This would allow the length of the mandrel 24 to be adjusted to accommodate stents of various sizes.

The term inner diameter of stent is defined as the inner diameter of the stent as measured when positioned on the fixture-support 20. Accordingly, if the stent is pre-expanded partially when positioned on the fixture-support 20, the measurement would be  
20 taken in the partial pre-expansion state. The partial pre-expansion of a stent allows for the spaces between the struts to increase, thereby preventing or reducing the formation of “cobwebs.” However, it would also allow for the composition to contact the inner

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surface of the stent. Accordingly, there is a tradeoff when expanding the stent prior to the application of the coating composition.

The outer diameter of the mandrel 24 can be smaller than the inner diameter of the stent 10 so as to prevent the outer surface of the mandrel 24 from making contact with the luminal surface of the stent 10. A sufficient clearance between the outer surface of the mandrel 24 and the luminal surface of the stent 10 should be provided to prevent the mandrel 24 from obstructing the pattern of the stent body during the coating process.

5 However, the outer diameter of the mandrel 24 should also be large enough to substantially shield the luminal surface of the stent 10 from spray coating. In other words, spray that would normally pass through the abluminal surface of the stent 10 and impact the luminal surface of the stent 10 will instead impact and coat the mandrel 24, as 10 will be discussed in further detail below in conjunction with FIG. 4A – FIG. 10C.

The lock member 26 includes a coning end portion 42 having an inwardly tapered angle  $\phi_2$ . Angle  $\phi_2$  can be the same as or different than the above-described angle  $\phi_1$ .

15 The coning end portion 42 supports the stent 10 at a second end during a coating process. A second end 44 of the mandrel 24 can be permanently affixed to the lock member 26 if the end 40 is disengagable from the support member 22. Alternatively, in accordance with another embodiment, the mandrel 24 can have a threaded second end 44 for screwing into a bore 46 of the lock member 26. The bore 46 can be of any suitable depth 20 that would allow the lock member 26 to be incrementally moved closer to the support member 22. The bore 46 can also extend completely through the lock member 26. Accordingly, stents 10 of any length can be securely pinched between the support and the lock members 22 and 26. In accordance with yet another embodiment, a non-threaded

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second end 44 and bore 46 combination is employed such that the second end 44 can be press-fitted or friction-fitted within the bore 46 to prevent movement of the stent 10 on the stent mandrel ~~fixture-support~~ 20.

In order to reduce coating defects at the point of contact between the stent 10 and

5 the ends 36 and 42, the ends 36 and 42 may be coated with or made of one or more polymeric materials having less adhesive force with the coating substance than the coating substance with the stent. Examples of suitable polymeric materials include poly (tetrafluor ethylene) (e.g., Teflon®), fluorinated ethylene propylene, poly (vinylidene fluoride), poly (*para* -xylyene), polyamide (Nylon), polyolefins (e.g., high density poly 10 (ethylene) and poly (propylene)), and polyacetal (DELRIN®). Of course the material used depends on the composition that is applied to the stent and the material from which the stent is made.

FIG. 3B illustrates a stent mandrel ~~fixture-support~~ 20B in accordance with another embodiment of the invention. The stent mandrel ~~fixture-support~~ 20B is substantially similar to the stent mandrel ~~fixture-support~~ 20 except that the ~~fixture-support~~ 20B includes a collet 48 in place of the lock member 26. The collet 48 comprises a coning end portion 49A coupled to a crimp section 49C via an arm 49E. The end portion 49A, like the end 42, is cone shaped and supports the stent 10 at a second end during a coating process. The bore extends completely through the collet 48, in which the mandrel 24 travels through. The crimp section 49C can be friction fitted to the mandrel 24 or crimped onto the mandrel 24 to prevent movement of the collet 48 with respect to the mandrel 24. Cutaway segments 49B and 49D enable the crimp section 49C to be easily crimped.

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FIG. 4A, FIG. 4B. and FIG. 4C illustrate a cross section, perspective view, and top view, respectively, of a body 50A of the stent mandrel 24. The shape of this embodiment is herein after defined as “configuration 1”. The body 50A (as well as 50B, 50C, 50D, 50E, 50F, and 50G -- collectively “50”) is the portion of the mandrel 24 that is not inserted into ends 36 and 42 during the coating process. If the mandrel 24 is used by itself, without any of the previously described elements such as the support member 22 or the lock member 26, the body 50 could be considered the mandrel 24 in and of itself.

Accordingly, the body 50 could be almost as long as the length of the stent. If flat ends, instead of the coning end portions 36 and 42, are used, then the length of the body 50 would be equivalent to or the same as the length of the stent. In one embodiment, the body 50 can have a length larger than the length of the stent. In some embodiments, the length of the body 50 should be more than 25% of the length of the stent, more than 50% of the length of the stent, more than 75% of the length of the stent, or more than 90% of the length of the stent. In one embodiment, the body 50A is cylindrical in shape and has a diameter slightly less than an inner diameter of the stent 10. In an embodiment of the invention, the diameter of the body 50A can be about 1.35 mm to about 1.4 mm less than the inner diameter of the stent 10 as indicated by distance 52. Note that the distance 52 is critical as too short a distance between the stent 10 and the body 50A may cause the spray composition 55 to wick underneath the stent struts and/or may form a film between the stent struts. Either way, this may cause the stent 10 to be stuck to the mandrel body 50A, which can lead to coating defects when the stent 10 is removed from the mandrel fixture support 20. Too large a distance 52 will lead to coating of the luminal surface of

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the stent 10. The proper distance does, in part, depend on the type of composition used and one having ordinary skill on the art can easily calibrate the distance.

During a coating process, a sprayed composition 55 is sprayed onto the stent 10. The spray composition 55 impacts and coats the abluminal surface of the stent 10. In 5 addition, some of the spray composition 55 passes through the gaps of the scaffolding network and impacts the body 50A, which acts to block the spray composition 55 from impacting, and therefore coating, the luminal surface of the stent 10.

The components of the coating substance or composition 55 can include a solvent or a solvent system comprising multiple solvents; a polymer or a combination of 10 polymers; and optionally a therapeutic substance or a drug or a combination of drugs.

Representative examples of polymers that can be used to coat a stent or medical device include ethylene vinyl alcohol copolymer (commonly known by the generic name EVOH or by the trade name EVAL); poly(hydroxyvalerate); poly(L-lactic acid); polycaprolactone; poly(lactide-co-glycolide); poly(glycerol-sebacate); 15 poly(hydroxybutyrate); poly(hydroxybutyrate-co-valerate); polydioxanone; polyorthoester; polyanhydride; poly(glycolic acid); poly(D,L-lactic acid); poly(glycolic acid-co-trimethylene carbonate); polyphosphoester; polyphosphoester urethane; poly(amino acids); cyanoacrylates; poly(trimethylene carbonate); poly(iminocarbonate); copoly(ether esters) (e.g. PEO/PLA); polyalkylene oxalates; polyphosphazenes; 20 biomolecules, such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid; polyurethanes; silicones; polyesters; polyolefins; polyisobutylene and ethylene-alphaolefin copolymers; acrylic polymers and copolymers; vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether;

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polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile; polyvinyl ketones; polyvinyl aromatics, such as polystyrene; polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrilestyrene

5      copolymers, ABS resins, and ethylene-vinyl acetate copolymers; polyamides, such as Nylon 66 and polycaprolactam; alkyd resins; polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; polyurethanes; rayon; rayon-triacetate; cellulose; cellulose acetate; cellulose butyrate; cellulose acetate butyrate; cellophane; cellulose nitrate; cellulose propionate; cellulose ethers; and carboxymethyl cellulose.

10      “Solvent” is defined as a liquid substance or composition that is compatible with the polymer and is capable of dissolving the polymer at the concentration desired in the composition. Examples of solvents include, but are not limited to, dimethylsulfoxide, chloroform, acetone, water (buffered saline), xylene, methanol, ethanol, 1-propanol, tetrahydrofuran, 1 -butanone, dimethylformamide, dimethylacetamide, cyclohexanone, 15      ethyl acetate, methylethylketone, propylene glycol monomethylether, isopropanol, isopropanol admixed with water, N-methyl pyrrolidinone, toluene, and mixtures and combinations thereof.

20      The therapeutic substance or drug can be for inhibiting the activity of vascular smooth muscle cells. More specifically, the active agent can be aimed at inhibiting abnormal or inappropriate migration and/or proliferation of smooth muscle cells for the inhibition of restenosis. The drug can also include any substance capable of exerting a therapeutic or prophylactic effect. For example, the agent can be for enhancing wound healing in a vascular site or improving the structural and elastic properties of the vascular

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site. Examples of agents include antiproliferative substances such as actinomycin D, or derivatives and analogs thereof (manufactured by Sigma-Aldrich 1001 West Saint Paul Avenue, Milwaukee, WI 53233; or COSMEGEN available from Merck). Synonyms of actinomycin D include dactinomycin, actinomycin IV, actinomycin I<sub>1</sub>, actinomycin X<sub>1</sub>, and actinomycin C<sub>1</sub>. The active agent can also fall under the genus of antineoplastic, antiinflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, antiallergic and antioxidant substances. Examples of such antineoplastics and/or antimitotics include paclitaxel (e.g. TAXOL<sup>®</sup> by Bristol-Myers Squibb Co., Stamford, Conn.), docetaxel (e.g. Taxotere<sup>®</sup>, from Aventis S.A., Frankfurt, Germany) 10 methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (e.g. Adriamycin<sup>®</sup> from Pharmacia & Upjohn, Peapack N.J.), and mitomycin (e.g. Mutamycin<sup>®</sup> from Bristol-Myers Squibb Co., Stamford, Conn.). Examples of such antiplatelets, anticoagulants, antifibrin, and antithrombins include sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, 15 forskolin, vaprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors such as Angiomax<sup>TM</sup> (Biogen, Inc., Cambridge, Mass.). Examples of such cytostatic or 20 antiproliferative agents include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (e.g. Capoten<sup>®</sup> and Capozide<sup>®</sup> from Bristol-Myers Squibb Co., Stamford, Conn.), cilazapril or lisinopril (e.g. Prinivil<sup>®</sup> and Prinzide<sup>®</sup> from Merck & Co., Inc., Whitehouse Station, NJ); calcium channel blockers (such as nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine

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antagonists, lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug, brand name Mevacor® from Merck & Co., Inc., Whitehouse Station, NJ), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. An example of an antiallergic agent is permilast potassium. Other therapeutic substances or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, dexamethasone, and rapamycin, and structural derivatives and functional analogues of rapamycin.

10 FIG. 5A, FIG. 5B, and FIG. 5C illustrate a cross section, perspective view, and top view, respectively, of a body 50B of the stent mandrel 24. The shape illustrated by FIG. 5A, FIG. 5B, and FIG. 5C is defined hereinafter as “configuration 2.” The cross section of body 50B at any cut along the length of the body 50B is in the shape of a 4-point star having 4 spines or spikes 56A, 56B, 56C, and 56D. The spikes 56A – 56D, 15 each defined by a pair of converging walls or sides so as to have a triangular shape, are evenly spaced within the circumference of the stent 10 (for example, at 90 degree intervals). Each spike 56A-56D converges with the adjacent spike at an angle; however, a curved transition between adjacent sides of neighboring spikes can also be provided. The body 50B, like the body 50A, acts to block the luminal surface of the stent 10 from 20 being coated by the spray composition 55. The outer most point of the body 50B (i.e., the tip of a spike 56) is separated from the inner surface of the stent 10 by about a distance of 1.35 mm to about 1.4 mm, as indicated by the distance 52. The body 50B may be advantageous over the body 50A as the body 50B limits the possibility of stent

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10/body 50B contact to only the points of the star shape instead of the full circumference of the cylinder shape of the body 50A. If there is any contact between the stent 10 and the spikes 56A – 56D, the contact area will only be along a line corresponding to the length of the peak of one or more of the spikes 56A – 56D, thereby limiting sticking and

5 the potential for defect formation. If a coating defect is formed, it will be limited to the line and can be fixed through subsequent coating or processing applications. It will be appreciated by one of ordinary skill in the art that the body 50B can include a minimum of three spikes or have additional spikes. The body 50B can be made by etching, laser or carving of a single solid piece of material. Alternatively, as illustrated by FIG. 5D, an

10 elongated core piece having a rectangular or square cross section can be provided and spikes 56A – 56D can be coupled by an adhesive or soldering to each of the four circumferential sides of the core piece.

In another embodiment, a body 50C can have configuration as shown in FIG. 6A – FIG. 6C. FIG. 6A illustrate a “+” shaped cross sectional configuration made of 4 15 rectangular walls 57A, 57B, 57C and 57D converging at one end and each separated by 90° from the adjacent wall. If 4 walls are used, the angle of convergence between two of the wall can be less than 90° so as to provide an “X” shaped cross sectional configuration. The “+” and “X” shape are defined hereinafter as “configuration 3.”

FIG. 7A, FIG. 7B. and FIG 7C illustrate a cross section, perspective view, and top 20 view, respectively, of a body 50D of the stent mandrel 24 in accordance with yet another embodiment of the invention. The body 50D has a shape of a 3-point star, i.e., the body 50D has three spikes 58A, 58B, and 58C. A side of each spike 58 converges at an angle with the adjacent side of its neighboring spike 58. The spikes 58A, 58B and 58C are

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spaced in even intervals within the circumference of the stent 10 (i.e., at 120 degree intervals). The body 50D can be made from a single solid piece or can be made from, as illustrated by Figure 7D, a elongated core section having a triangular cross section such that the spikes 58A-58C are attached or coupled to each side of the core section. The 5 shape provided by FIGs. 7A-7D is defined herein after as “configuration 4.”

It should be noted that in some embodiments the mandrel 24 or the body 50 can contact the inner stent surface. As best illustrated by FIG. 7A, spikes 58A – 58C of the body 50D touch and support the luminal surface of the stent 10, thereby obviating the need for the ends 36 and 42 to be cone-shaped to support the stent 10. In the embodiment 10 were body 50 makes contact with the inners surface of the stent, the body may be coated with or made of a non-stick material such as poly (tetrafluor ethylene) (e.g., Teflon®). Alternative materials such as fluorinated ethylene propylene (“FEP”), poly (vinylidene fluoride) (“PVDF”), poly (*para* -xylylene), polyamide (Nylon), polyolefins (e.g., high density poly (ethylene) and poly (propylene)), or polyacetal (DELRIN®) can also be 15 used, depending on the coating composition employed. The polymeric material can prevent or reduce the formation of clumps or other defects along the point of contact between the stent 10 and the fixture-support.

In lieu of spike shaped walls forming a “star” shaped cross section, the spikes could be curved such that the cross section of the body 50 would resemble a 4 leaf 20 clover, as depicted in FIG. 8A – FIG. 8C. The entire wall could be curved (as illustrated) or the wall can include 2 parallel sides having a curved end. These shapes are defined as “configuration 5.” The radius of curvature of the walls, more particularly the end of the walls, can be less than the radius of curvature of the stent so as to provide for minimum

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contact between the mandrel 24 and the stent. The body 50E is similar in form and function to the body 50B and therefore has similar advantages over the body 50A. It will be appreciated by one of ordinary skill in the art that the body 50E can have 3 leaves or more than 4 leaves.

5 FIG. 9A, FIG. 9B, and FIG 9C illustrate a cross section, perspective view, and top view, respectively, of a section 50F of the stent mandrel 24 according to another embodiment of the invention. This shape is defined as “configuration 6.” Body 50F is an elongated cubical shaped mandrel having a square or rectangular cross sectional configuration. In one embodiment, the longest diagonal of the cross section (the 10 measurement from one corner to the opposing corner) can be smaller than the inner diameter of the stent 10 so as to provide a distance 52 between a corner of the section 50F and the luminal surface of the stent 10.

FIG. 10A, FIG. 10B, and FIG 10C illustrate a cross section, perspective view, and top view, respectively, of a section 50G of the stent mandrel ~~fixture-support~~ 24 according 15 to yet another embodiment of the invention. The section 50G includes a wall 59 that wraps around a core of the mandrel in a spiral or cork-screw like fashion. The wall 59 can be in contact with the inner surface of the stent 10. Alternatively, the mandrel can be designed so that there is minimal distance between the wall 59 and the inner surface of the stent 10. The wall 59 can be partially wrapped around the core or can be wrapped 20 more than once all the way around the core. The wall 59 need not be continuous as illustrated by FIG. 10B. The wall 59 can be cylindrical in shape or plate-like. All these shapes are defined as “configuration 7.”

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FIG. 11A, FIG. 11B and FIG. 11C illustrate the resulting luminal surface coating of stents after a conducted experiment using a conventional stent mandrel fixture-support, a stent mandrel fixture-support with section 50A diameter of 0.061 inches, and a stent mandrel fixture-support with a section 50A diameter of 0.0625 inches, respectively.

5 In the conducted experiment, the process parameters are listed in Table I below. PEA Benzyl Ester (300  $\mu$ g) was coated onto 12 mm small VISION stents (available from Guidant Corp.) from a 2 wt% PEA Benzyl Ester in ethanol (200 proof) formulation. Coating flow rates were approximately 20  $\mu$ g/pass. The stents were oven baked at 50°C for 1 hour. Results indicated that the abluminal stent coatings were not effected affected 10 using a stent mandrel fixture-support having a section 50A with diameter of 0.061 and 0.0625 inches. However, luminal stent coating was significantly reduced as the diameter of the section 50A is increased. The larger diameter pin was able to “shield” the inner diameter stent surface from much of the atomized spray solution. FIG 11A, 11B, and 11C provides a qualitative overview of the inner diameter coating thickness reduction 15 observed when the inventive mandrels are implemented.

**Table I** Process parameters for spray coating PEA Benzyl Ester.

Parameter	Set Value	Units
<b>Spray Head</b>		
Spray nozzle temperature	Ambient	°C
Atomization pressure (non-activated)	15±2.5	psi
Distance from spray nozzle to mandrel pin	15	mm
Solution barrel pressure	2-3	psi
Needle valve lift pressure	80±10	psi
Relative humidity near spray head	<45	%
<b>Heat Nozzle</b>		
Temperature	80	°C
Air Pressure	12-15	psi
Distance from heat nozzle to mandrel pin	10-15	mm

While particular embodiments of the present invention have been shown and described, it will be obvious to one of ordinary skill in the art that changes and 5 modifications can be made without departing from this invention in its broader aspects. For example, after application of the coating to the abluminal surface of the stent 10 as described above, the luminal surface of the stent 10 can be coated with a different coating via spray coating, electroplating or other technique. Therefore, the appended claims are to encompass within their scope all such changes and modifications as fall within the true 10 spirit and scope of this invention.

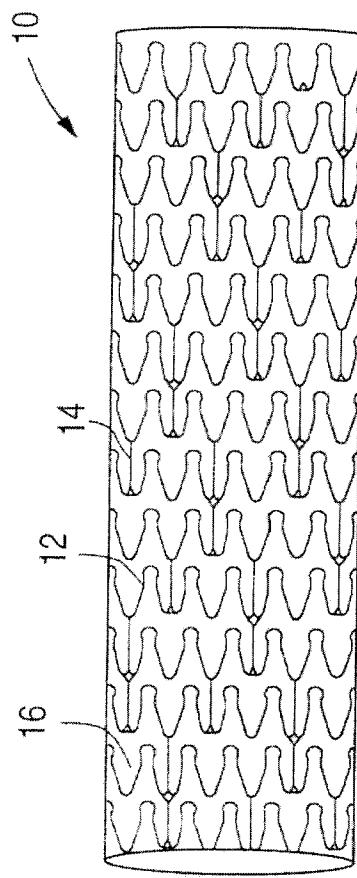


FIG. 1  
Prior Art

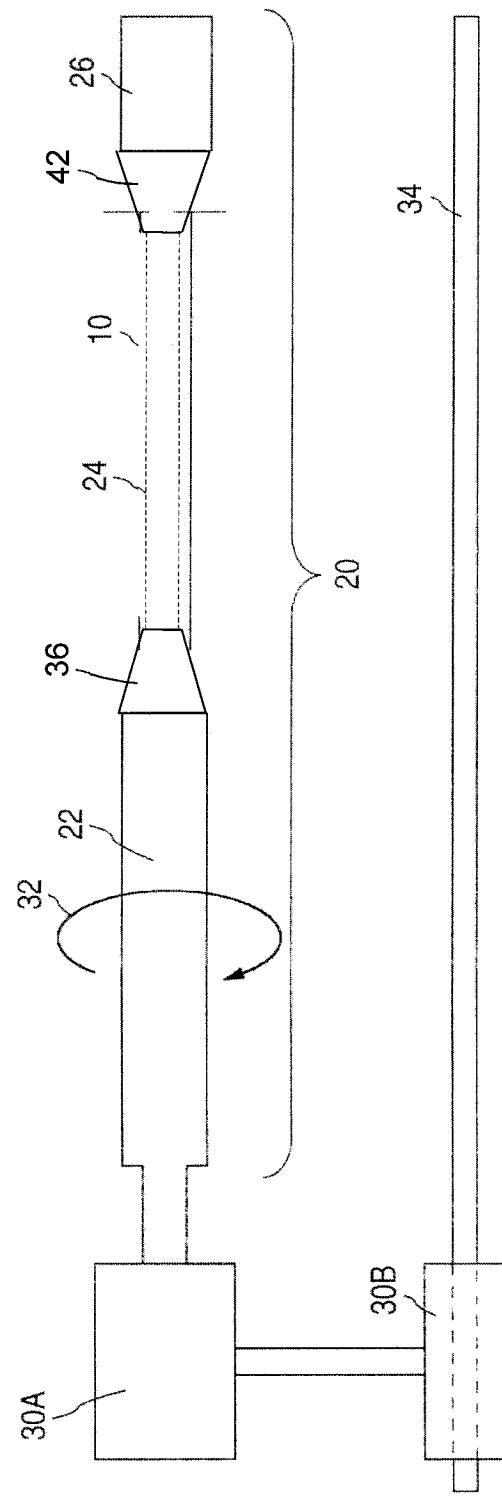


FIG. 2

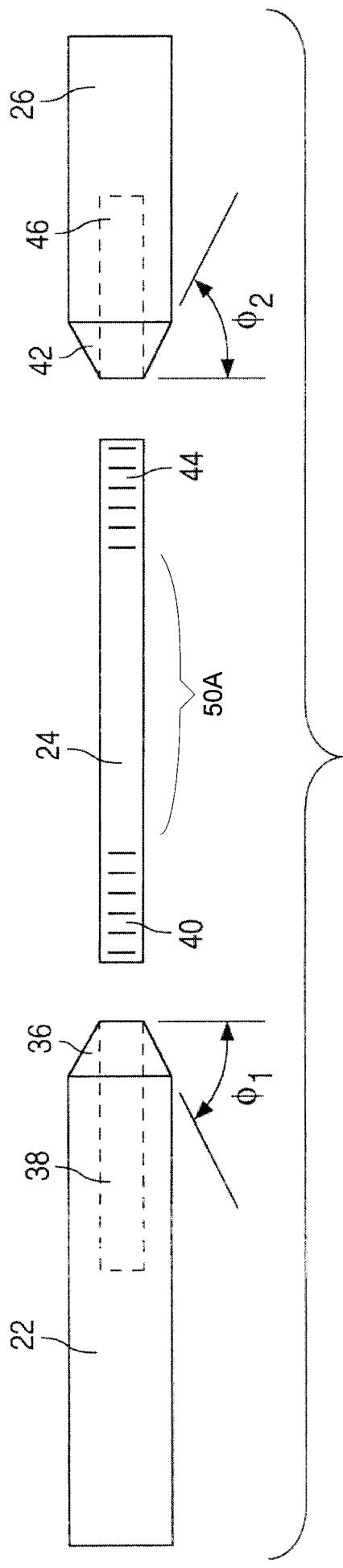


FIG. 3A

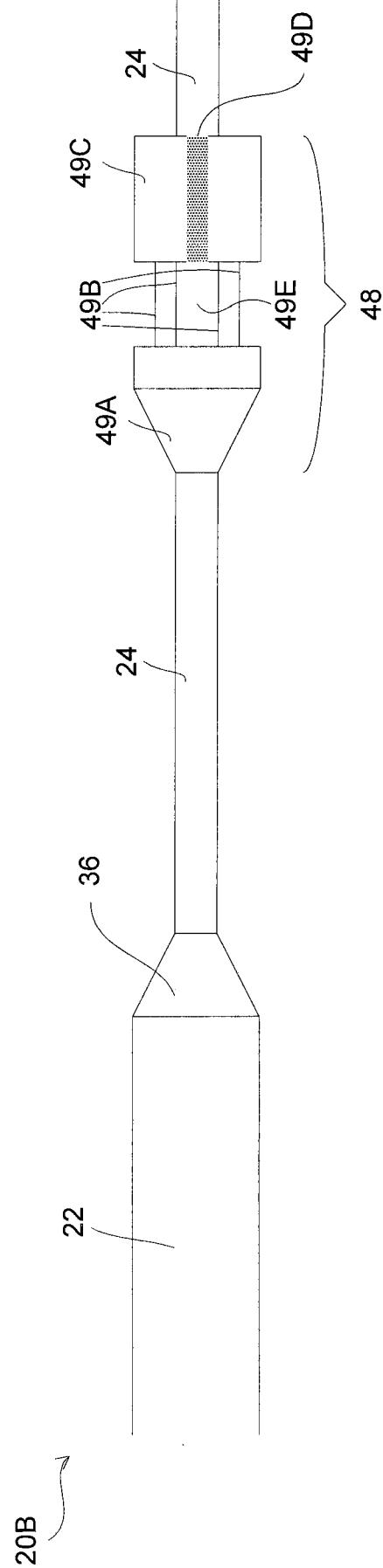
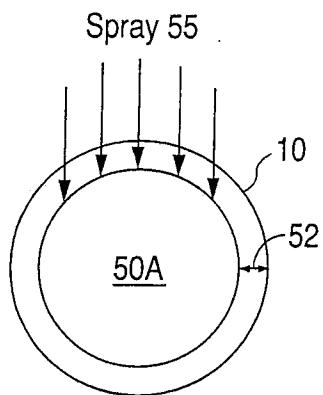
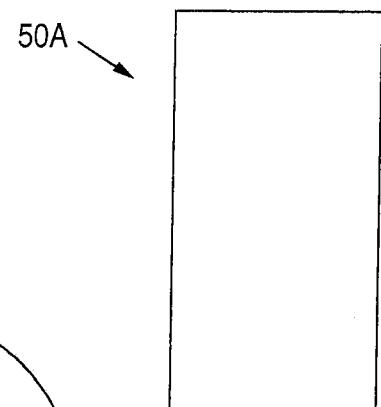


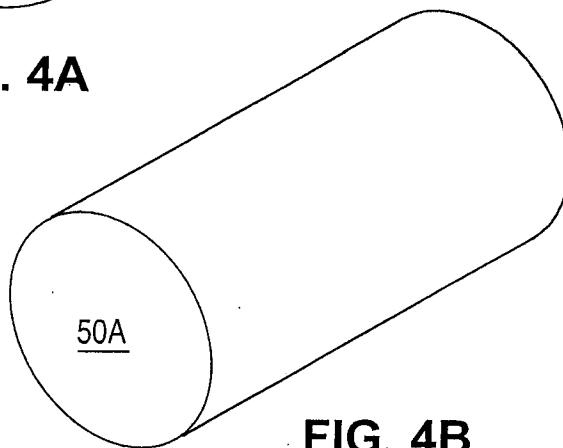
FIG. 3B



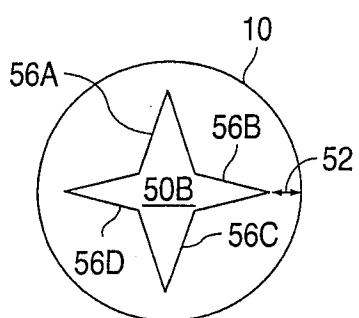
**FIG. 4A**



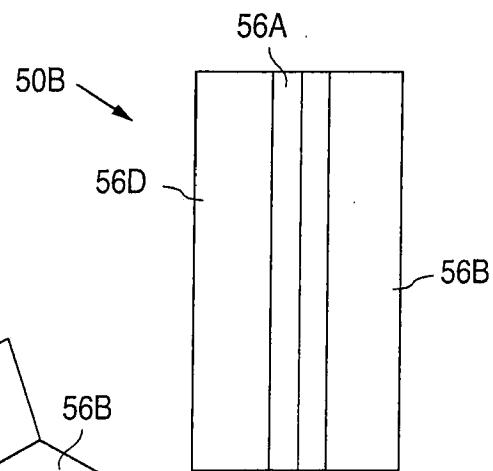
**FIG. 4C**



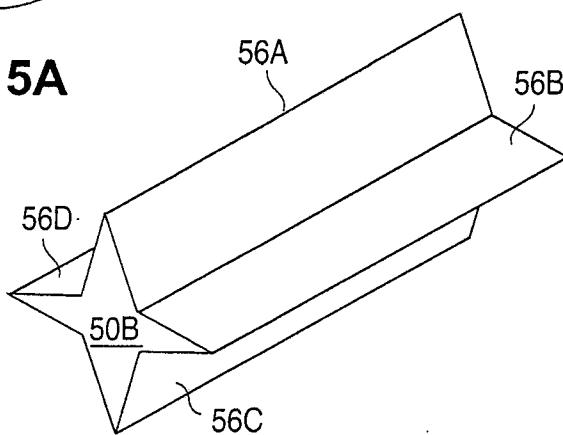
**FIG. 4B**



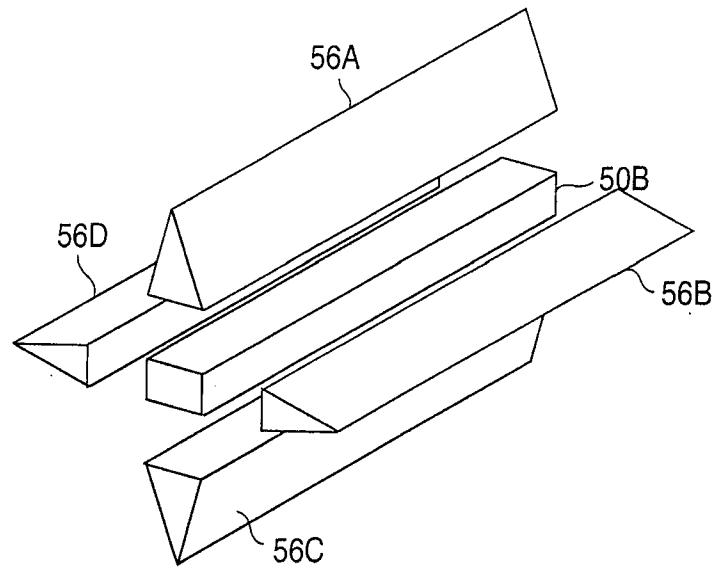
**FIG. 5A**



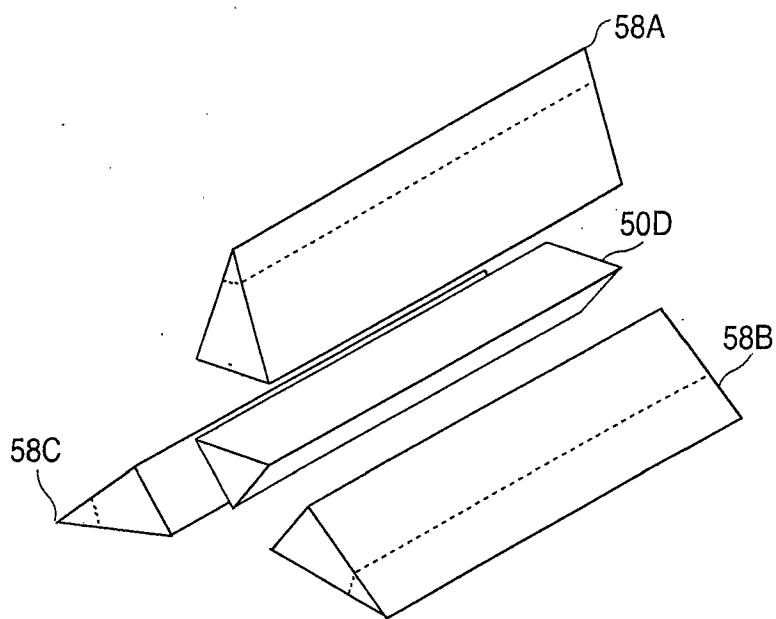
**FIG. 5C**



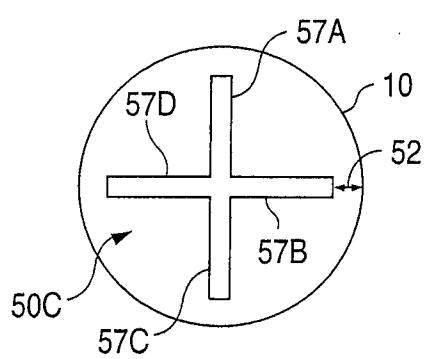
**FIG. 5B**



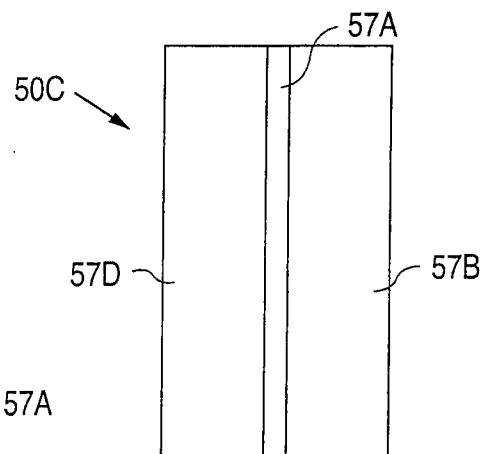
**FIG. 5D**



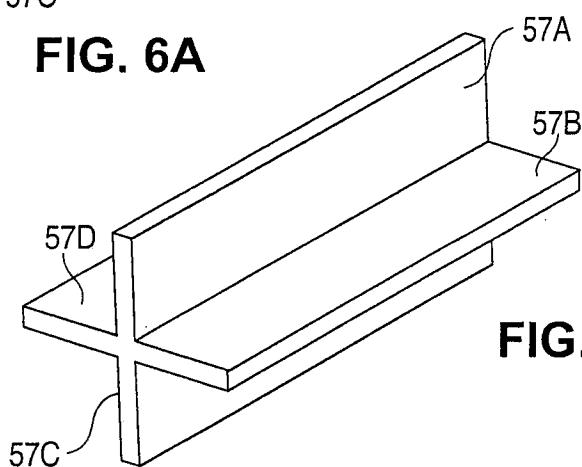
**FIG. 7D**



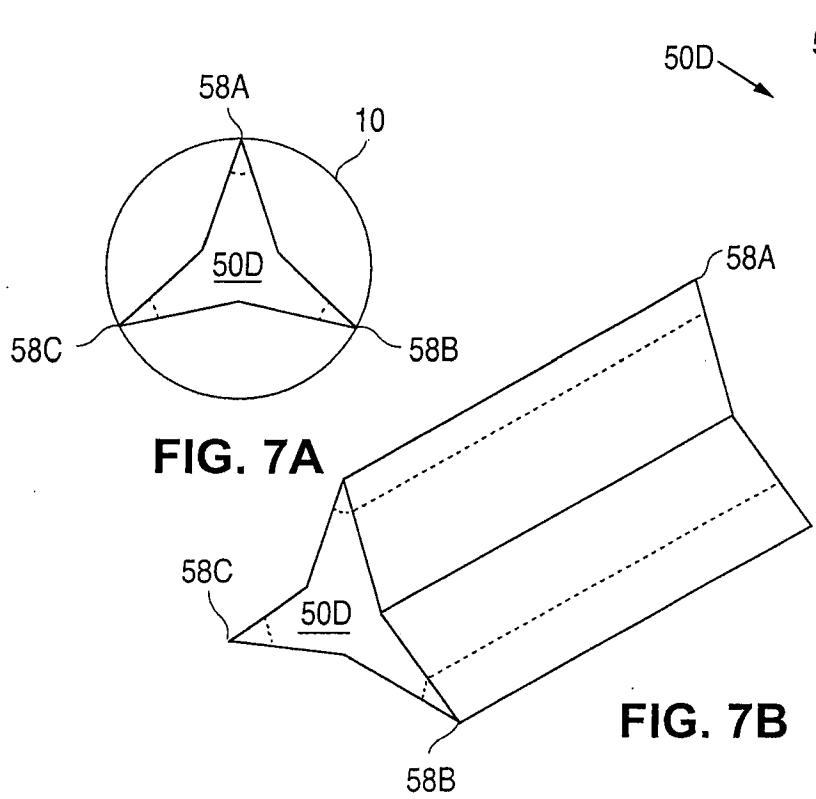
**FIG. 6A**



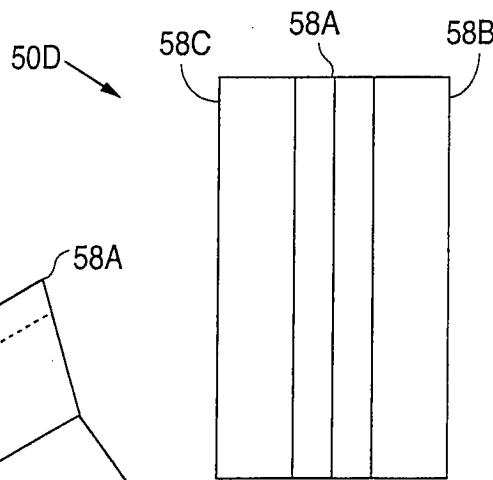
**FIG. 6C**



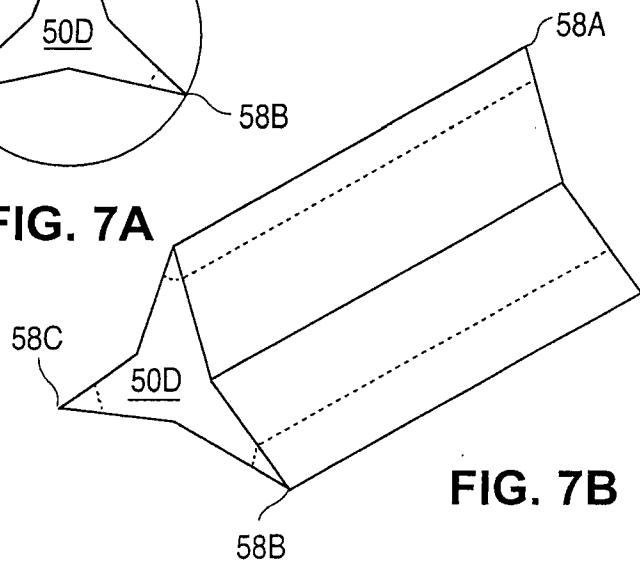
**FIG. 6B**



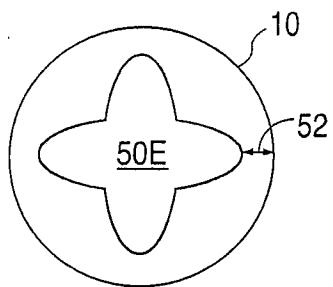
**FIG. 7A**



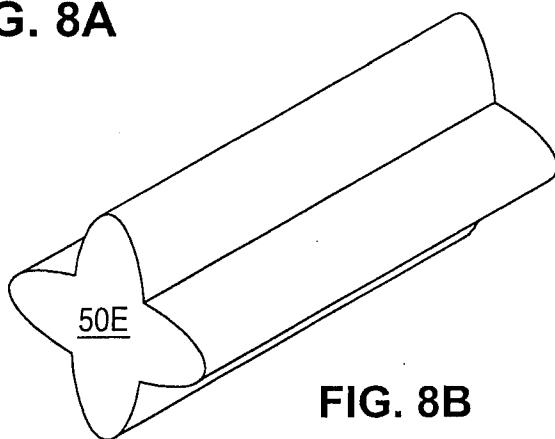
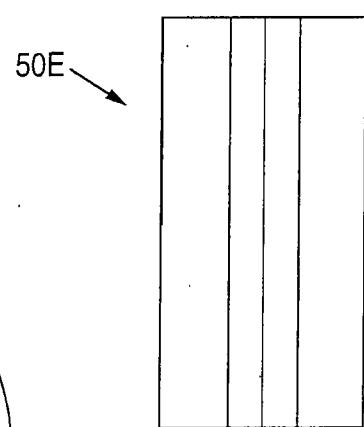
**FIG. 7C**



**FIG. 7B**

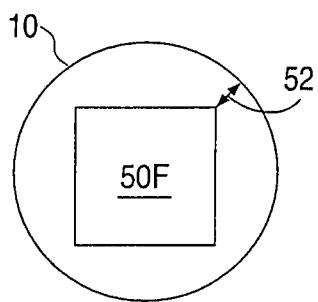


**FIG. 8A**

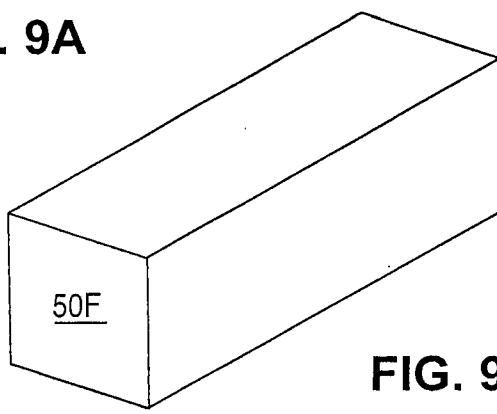
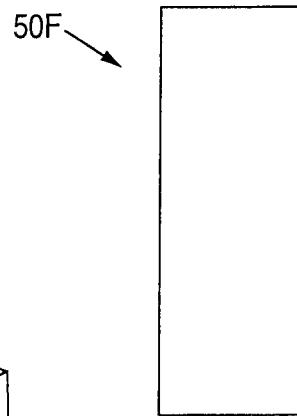


**FIG. 8B**

**FIG. 8C**

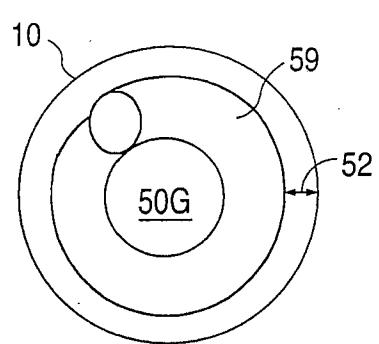


**FIG. 9A**

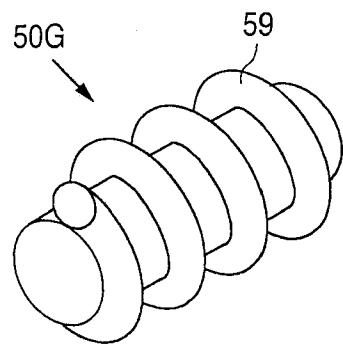


**FIG. 9B**

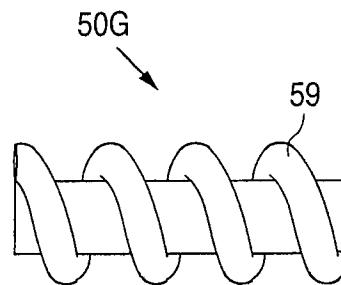
**FIG. 9C**



**FIG. 10A**

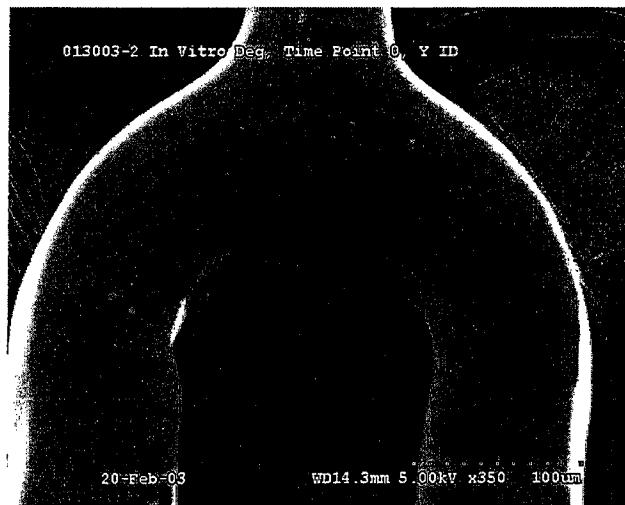


**FIG. 10B**



**FIG. 10C**

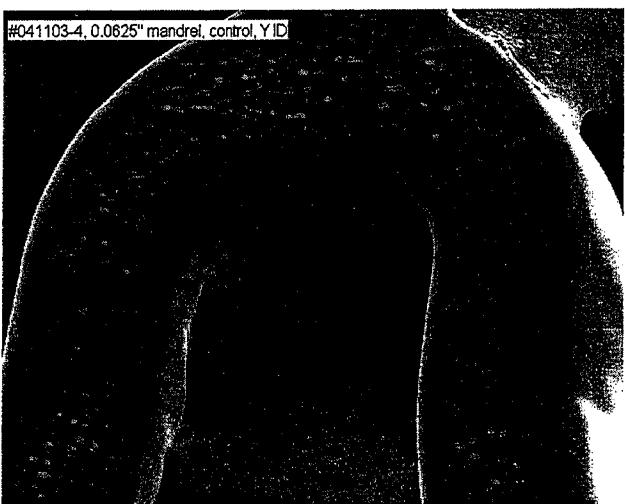
**FIG. 11a**



**FIG. 11b**



**FIG. 11c**



# EXHIBIT B

# United States Patent [19]

Hattler et al.

[11] Patent Number: 4,846,791

[45] Date of Patent: Jul. 11, 1989

[54] MULTI-LUMEN CATHETER

[75] Inventors: Brack G. Hattler; Irvin Furman, both of Denver, Colo.

[73] Assignee: Advanced Medical Technology & Development Corp., Denver, Colo.

[21] Appl. No.: 241,070

[22] Filed: Sep. 2, 1988

[51] Int. Cl. 4 A61M 25/00

[52] U.S. Cl. 604/43; 604/53; 604/158; 128/343

[58] Field of Search 604/43-65, 604/51-53, 158-170, 280-283; 128/343

[56] References Cited

U.S. PATENT DOCUMENTS

3,584,624	6/1971	De Ciutis	604/170 X
3,598,118	8/1971	Warren	604/53
4,180,068	12/1979	Jacobsen et al.	604/44
4,203,436	5/1980	Grimsrud	604/44
4,402,684	9/1983	Jessup	604/43 X
4,738,658	4/1988	Magro et al.	604/280 X

FOREIGN PATENT DOCUMENTS

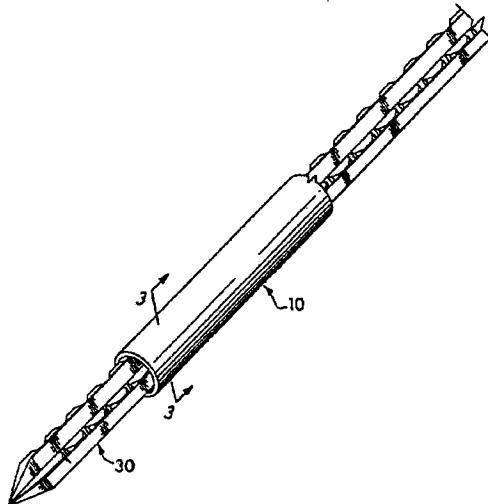
592192 7/1925 France ..... 604/44

Primary Examiner—Dalton L. Truluck  
Attorney, Agent, or Firm—Dorr, Carson, Sloan & Peterson

[57] ABSTRACT

A multi-lumen catheter is formed by first introducing one end of an expandable tube into the blood vessel. A divider is then inserted into the distal end of the tube and extends the length of the tube, thereby dividing the tube into a plurality of the separate lumens. Insertion of the divider causes radial expansion of the tube which substantially seals the opening in the wall of the vessel. In one embodiment, the divider has a hollow triangular cross-section which creates four separate lumens. A series of raised protrusions extending outwardly from the sides of the divider prevent collapse of the tube against the divider.

24 Claims, 6 Drawing Sheets



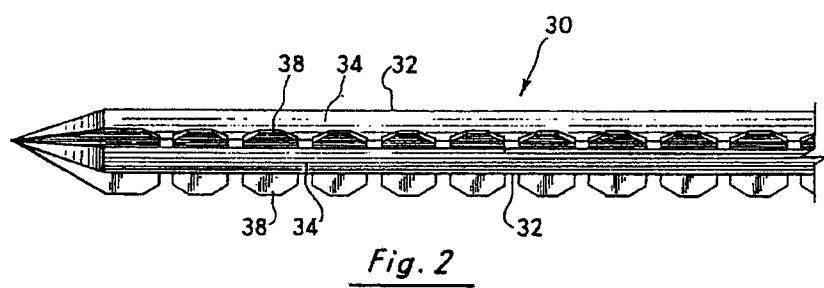
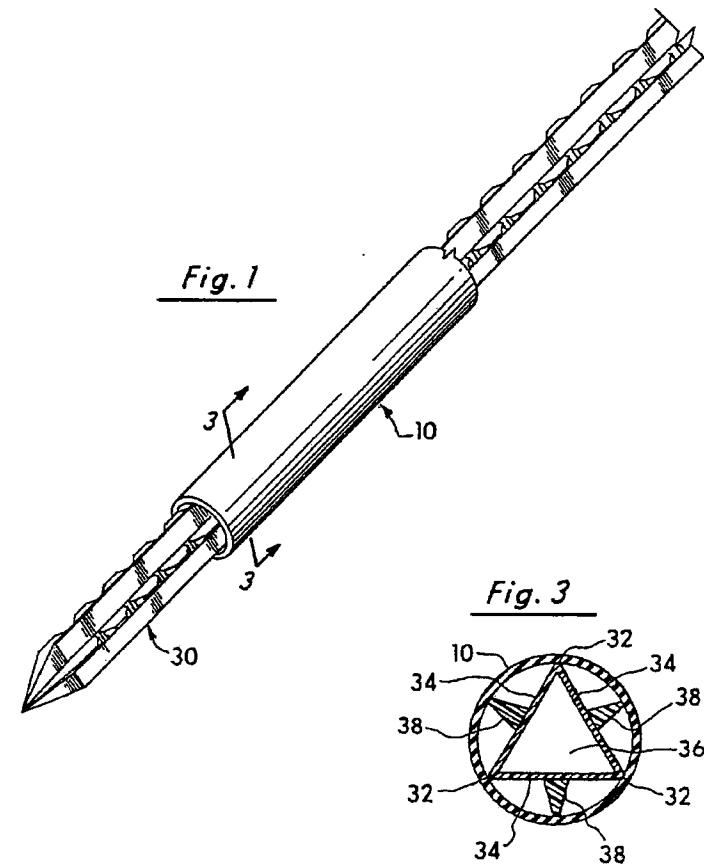


Fig. 4

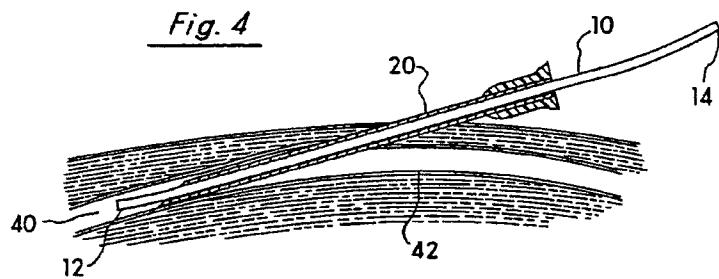


Fig. 5

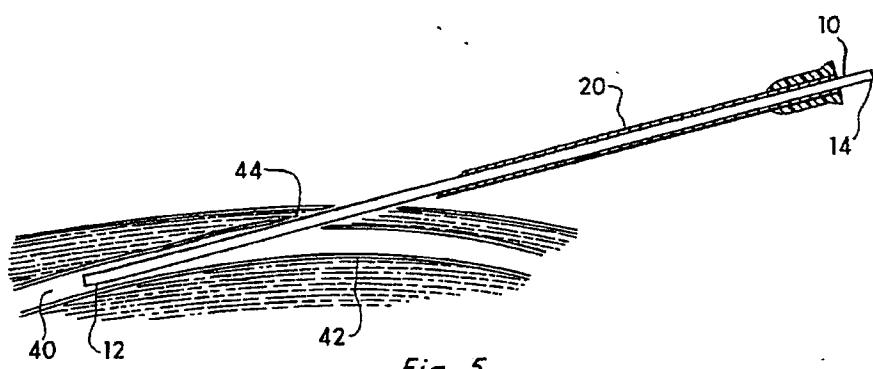
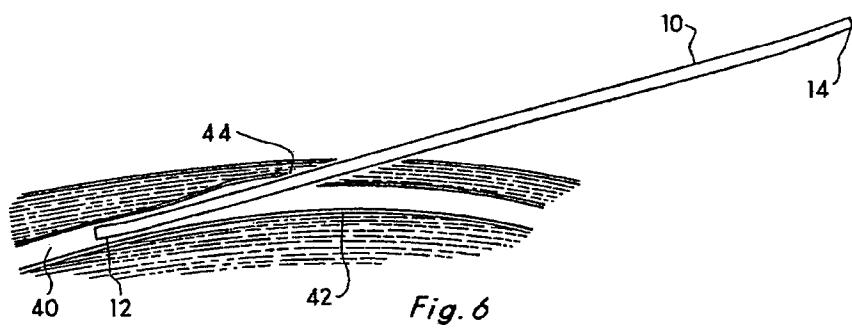
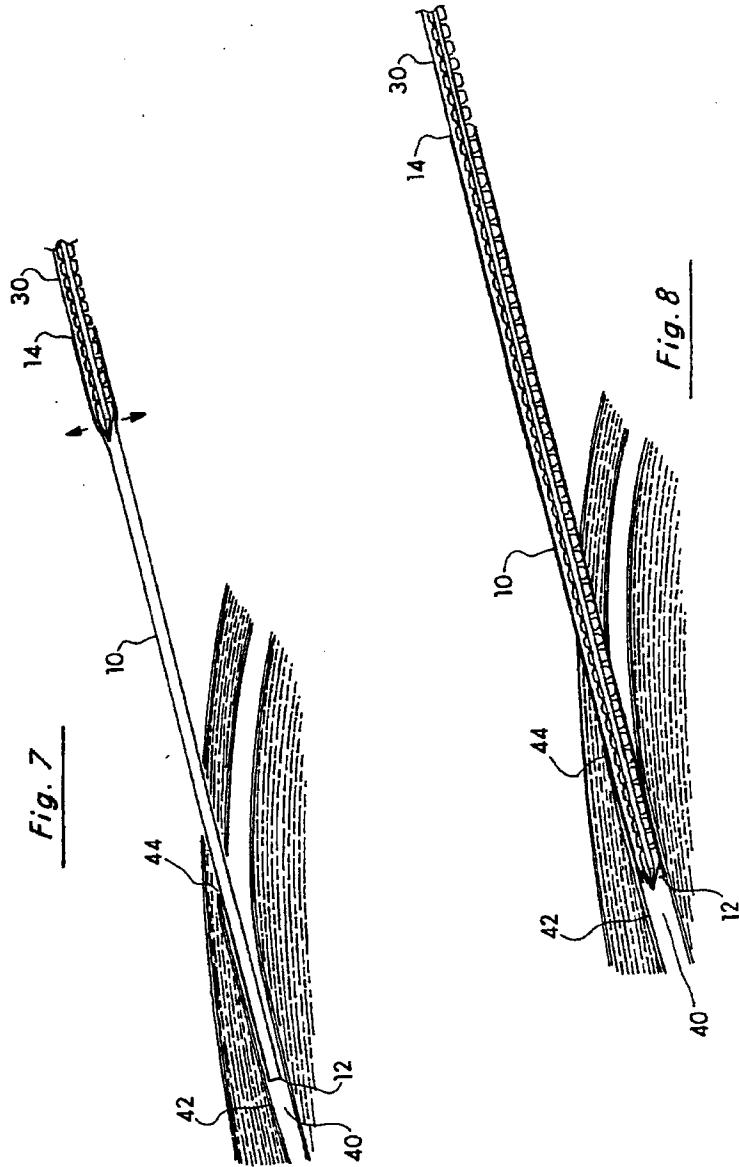
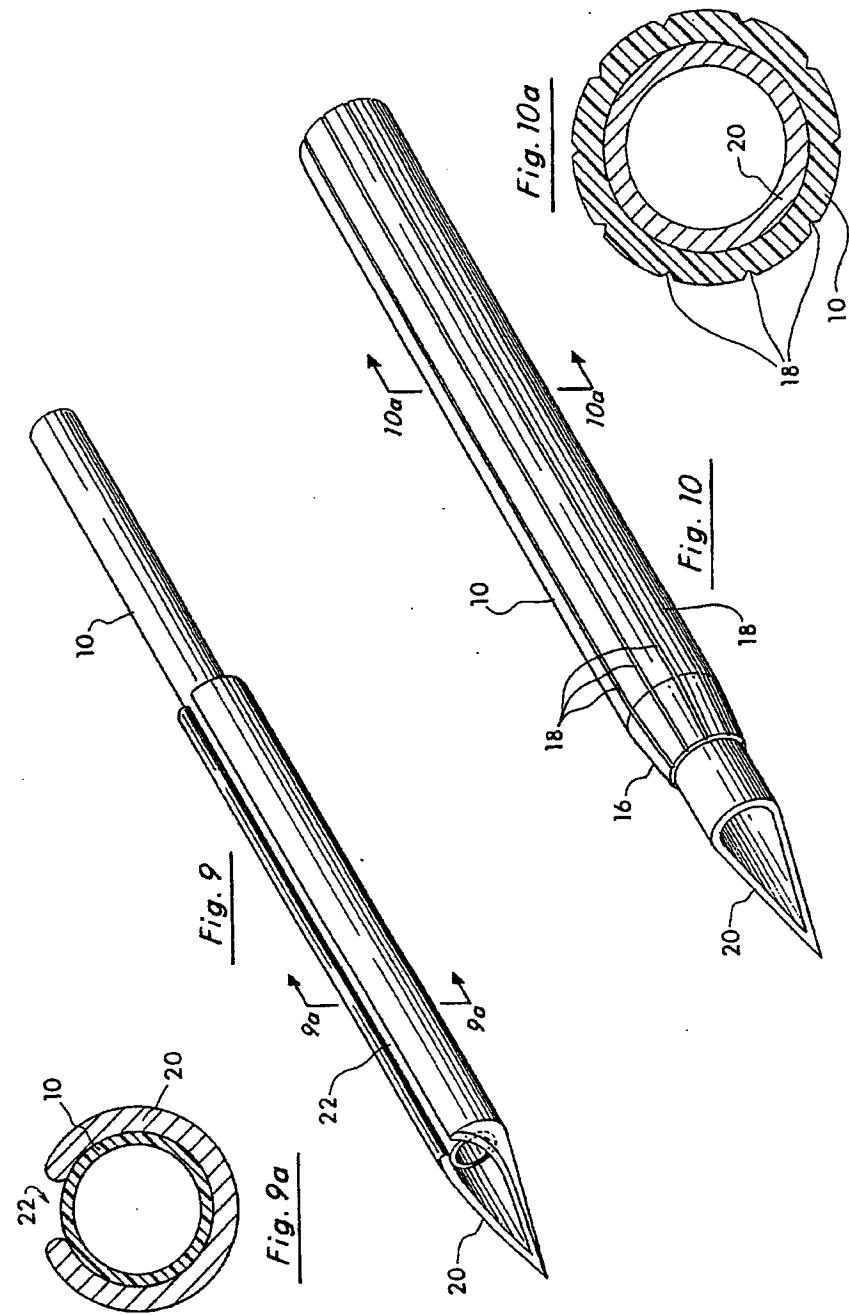
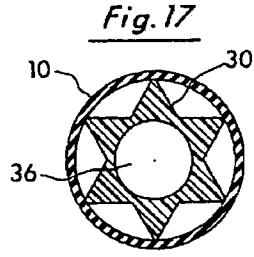
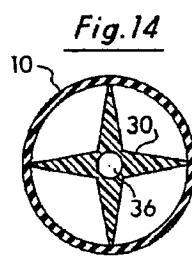
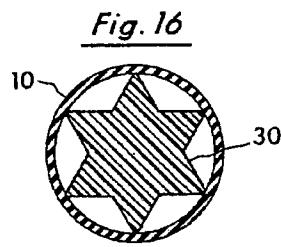
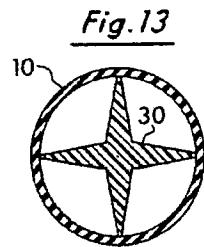
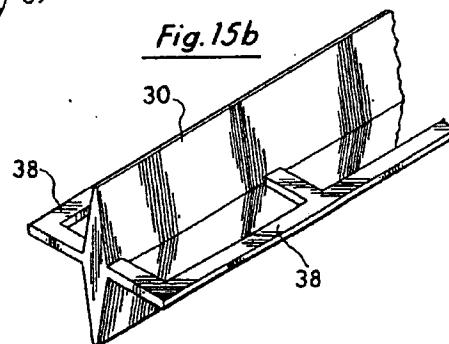
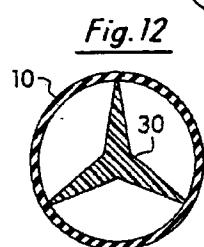
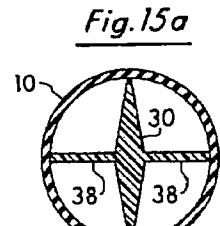
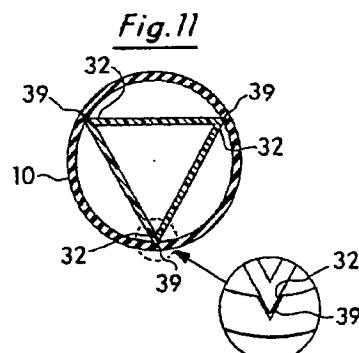


Fig. 6









U.S. Patent

Jul. 11, 1989

Sheet 6 of 6

4,846,791

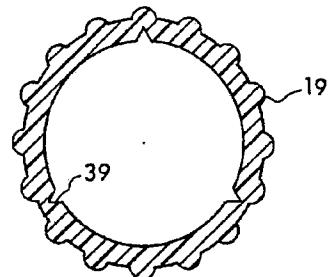


Fig. 18

## MULTI-LUMEN CATHETER

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

The present invention relates generally to the field of catheters, and in particular to catheters having multiple fluid carrying passageways.

## 2. Statement of the Problem.

Catheters of many types and configurations have been known and used for a number of years. Catheters function to carry fluids into and out from the blood vessel of a patient. One problem associated with catheters is the physical trauma and associated discomfort to the patient caused by insertion of the catheter and maintenance of the catheter in the patient for a period of time. Another problem associated with catheters is the risk of infection to the patient. These problems are multiplied when a number of catheters are inserted either at the same time or over a period of time. One approach to these problems has been to use a single catheter having multiple fluid carrying passageways, or lumens. This allows a number of different medications to be administered to the patient at one time using the same catheter.

A prior art search conducted by the inventor of the present invention disclosed a variety of multi-lumen catheters having various functions, as follows:

Inventor	U.S. Pat. No.	Issue Date
Hattler, et al.	4,406,656	9-27-83
Curelaru, et al.	4,581,019	4-8-86
Ekholmer	4,717,379	1-5-88
Luther	4,668,221	5-26-87
DeVries, et al.	4,596,548	6-24-86
Daugherty, et al.	4,588,398	5-13-86
Suzuki	4,565,545	1-21-86
Blake	4,465,481	8-14-84
Blake, et al.	4,398,910	8-16-83
Brown, et al.	4,581,012	4-8-86

U.S. Pat. No. 4,406,656 issued to Hattler, et al., discloses on type of multi-lumen catheter in which a plurality of collapsible lumens are mounted around the periphery of a central flexible lumen that is capable of retaining its shape with or without fluid flow. Each collapsible lumen is capable of expanding when fluid is flowing therein to a much greater cross-sectional area than in its collapsed state.

U.S. Pat. No. 4,717,379 issued to Ekholmer discloses a catheter having a number of passages surrounding a central lumen. A series of perforations from these passages to the outside of the catheter enable a lubricant cream or gel stored in the passages to pass through the perforations and coat the surface of the catheter to ease insertion.

U.S. Pat. No. 4,668,221 issued to Luther pertains to the assembly of a stylet and catheter. A solid stylet is mounted through the catheter to enable more accurate piercing of the blood vessel, and to reduce the possibility of double piercing the vein. The catheter is made of a hydrophilic polymer which expands from the stylet after contacting body fluids. This permits the stylet to be withdrawn while leaving the catheter in place in the vein. The possibility of a plurality of lumens in the catheter is discussed.

U.S. Pat. No. 4,596,548 issued to DeVries, et al., pertains to a single lumen venous catheter to be inserted into the atrium of the heart. Externally placed ribs or

dividers prevent the atrium of the heart from collapsing over the catheter opening to prevent blockage of the flow of blood into the catheter.

U.S. Pat. Nos. 4,581,019 issued to Curelaru, et al., 5 4,588,398 issued to Daugherty, et al., and 4,565,545 issued to Suzuki, all pertain to devices for insertion of single lumen catheters.

Finally, U.S. Pat. Nos. 4,398,910 and 4,465,481 issued to Blake, et al., and 4,581,012 issued to Brown, et al., relate generally to catheters having a plurality of lumens.

## Solution to the Problem

None of the prior art references uncovered in the search set forth the use of a divider that is separately inserted into the catheter tube after the tube has been introduced into the blood vessel, thereby providing multiple lumens for the catheter. Absent the divider, the catheter tube can be fitted within a relatively small diameter hollow needle for insertion into the blood vessel. Introduction of the catheter tube into the blood vessel in this manner minimizes the size of the opening created through the wall of the blood vessel, and accordingly minimizes trauma and discomfort for the patient. Subsequent insertion of the divider radially expands the catheter tube and seals the opening in the blood vessel wall around the catheter tube. This minimizes leakage of blood from the vessel, and thereby 30 reduces the risk of infection and hemorrhage.

## SUMMARY OF THE INVENTION

This invention provides an improved multi-lumen catheter in which one end of an expandable tube is first 35 introduced into a blood vessel through an opening in the wall of the blood vessel. A divider is subsequently inserted from the distal end of the tube and extends the length of the tube, thereby dividing the tube into a plurality of separate lumens. Insertion of the divider 40 causes radial expansion of the tube and seals the opening between the tube and the wall of the blood vessel. This offers the advantages of requiring a smaller hole through the wall of the blood vessel, thus minimizing trauma, discomfort, and the risk of infection to the patient. These and other advantages, features, and objects of the present invention will be more readily understood in view of the following detailed description and the drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present invention can be more readily understood in conjunction with the accompanying drawings, in which:

55 FIG. 1 is a perspective view showing the divider inserted through a catheter tube.

FIG. 2 is an side elevational view of the divider.

FIG. 3 is a front cross-sectional view of the divider inserted into the catheter tube.

FIG. 4 is a side cross-sectional view showing the needle and catheter tube inserted into the blood vessel. This is the first step of the sequence shown in FIGS. 4 60 through 8 demonstrating installation of the present multi-lumen catheter.

65 FIG. 5 is a side cross-sectional view showing retraction of the needle from inside the blood vessel, with the end of the catheter tube remaining inside the blood vessel.

FIG. 6 is a side cross-sectional view showing removal of the needle from the catheter following catheter tube.

FIG. 7 is a side cross-sectional view showing initial insertion of the divider into the distal end of the catheter tube.

FIG. 8 is a side cross-sectional view showing complete insertion of a divider extending the length of the catheter tube, causing radial expansion of the tube to substantially seal the opening between the tube and the wall of the blood vessel.

FIG. 9 is a perspective view showing an alternative embodiment of the present invention, in which a hollow needle having a slit extending its entire length is used to introduce the catheter tube into the blood vessel.

FIG. 9a is a cross-sectional view corresponding to FIG. 9.

FIG. 10 is a perspective view of an alternative embodiment of the present invention in which the catheter tube is a sleeve that fits over the insertion needle.

FIG. 10a is a cross-sectional view corresponding to FIG. 10.

FIG. 11 is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which a series of recessed grooves extending along the inner surface of the catheter tube act as guides for the edges of the divider.

FIG. 12 is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which the divider has a generally Y-shaped cross-section to create three lumens within the catheter tube.

FIG. 13 is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which the divider has a solid, cross-shaped cross-section to create four lumens within the catheter tube.

FIG. 14 is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which the divider has a hollow, cross-shaped cross-section to create five lumens within the catheter tube.

FIG. 15a is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which the divider is essentially a vertical bar that divides the catheter tube into two lumens. A series of raised protrusions extend outward from the midline of both faces of the divider to prevent collapse of the catheter tube against the faces of the divider.

FIG. 15b is a perspective view of the divider corresponding to FIG. 15a.

FIG. 16 is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which the divider has a solid, star-shaped cross-section to create six lumens within the catheter tube.

FIG. 17 is a cross-sectional view of the catheter tube and divider in an alternative embodiment of the present invention in which the divider has a hollow, star-shaped cross-section to create seven lumens within the catheter tube.

FIG. 18 is a cross-sectional view of an alternative embodiment of the catheter in which a series of recessed grooves extend along the inner surface of the catheter, and a series of raised ridges extend longitudinally along the outer surface of the catheter tube.

#### DETAILED DESCRIPTION OF THE INVENTION

FIGS. 4 through 8 illustrate the steps of installing a multi-lumen catheter in a blood vessel according to the present invention. FIG. 4 shows the first step in which the needle 20 and the end 12 of the catheter tube 10 are introduced into a blood vessel 40. The needle 20 punctures the wall 42 of the vessel and allows the end 12 of the catheter tube to be inserted through the needle into the interior of the blood vessel.

A conventional hollow stainless steel needle of the type commonly used in the medical field is satisfactory for inserting the catheter tube into the blood vessel. Needle sizes from 14 to 22 gauge are used depending upon the volume of the fluids involved. For example, larger diameters are necessary for central venous catheters. Smaller diameters are sufficient when dealing with smaller peripheral blood vessels.

The catheter tube is conventionally made of the flexible, expandable material such as amber latex, vinyl, or silicon rubber. The tube must have a proper outside diameter and rigidity to allow the tube to be slipped into the core of the needle with little or no restriction. The tube should have an outside diameter at least 0.005 inches smaller than the inside diameter of the insertion needle. The tube must also have sufficient flexibility to allow it to follow the natural curvature of the blood vessel.

Following insertion of the catheter tube, the needle 20 is then retracted out of the blood vessel, but the end of the catheter tube remains in place inside the blood vessel as shown in FIG. 5. Retraction of the needle leaves an annular opening 44 in the vessel wall 42 around the outside of the tube 10.

The next step is removal of the needle from the catheter tube as shown in FIG. 6. In one embodiment of the present invention, the needle is removed simply by sliding the needle back over the distal end 14 of the tube. Alternatively, a conventional "break away" needle can be employed that has lines of weakness or perforations extending the length of the needle. The needle readily separates into two halves along its major axis to facilitate removal from the catheter tube.

A divider 30 is then inserted into the catheter tube from the distal end 14 of the tube, as shown in FIG. 7, thereby dividing the tube into a plurality of separate lumens. Details of the preferred embodiment of the divider are illustrated in the perspective view of FIG. 1, in the side elevational view of FIG. 2, and in the front cross-sectional view of the divider and tube in FIG. 3. As the divider is inserted into the tube, each of the outer edges or corners 32 of the divider contact the inside surface of the tube to form a fluid-tight seal extending the length of the divider between adjacent lumens. In the preferred embodiment, the divider has a generally triangular, hollow cross-section. Three separate lumens 16 are created in the areas between the three sides 34 of the divider and the tube. A fourth, central lumen 36 is defined by the area within the divider.

The divider has cross-sectional dimensions slightly greater than the inside diameter of the catheter tube, thereby causing radial expansion of the tube as the divider is inserted, as shown in FIG. 7. FIG. 8 shows complete insertion of the divider 30 extending the entire length of the catheter tube 10. The cross-sectional dimensions of the divider should be selected with reference to the diameter of the needle 10 originally used to

insert the catheter tube into the blood vessel. Ideally, insertion of the divider into the tube should result in sufficient radial expansion of the tube to substantially close and seal the annular opening 44 in the wall of the blood vessel around the outside of the tube. In other words, the ultimate outside diameter of the tube, with the divider inserted, is at least slightly greater than the inside diameter of the insertion needle, and is ideally as great as the outside diameter of the insertion needle. Catheters vary widely in diameter, depending upon the specific application and the diameter of the blood vessel involved. However, in most cases, a relatively small radial expansion of the tube of approximately 0.005 to 0.010 inches will be sufficient to substantially seal the annular opening 44 in the wall of the blood vessel.

The divider can be made of nylon, teflon, or some other material having adequate anti-friction properties to allow easy insertion of the divider into the tube. The material selected must have adequate flexibility so that the combination of the tube and divider can follow the natural curvature of the blood vessel without causing undue trauma or discomfort to the patient. The divider material must also have sufficient memory to retain its desired shape following insertion into the tube.

Blood pressure within the vessel will tend to cause the tube to collapse against the sides of the divider unless the internal pressure of the peripheral lumens is at least as great as the external blood pressure. Collapse or substantial constriction of these peripheral lumens would interfere with effective administration of medication to the patient through the catheter. To avoid this problem, support means extend between the inside surface of the tube and the sides of the divider to maintain a minimum spacing between the tube and each of the sides of the divider. In the preferred embodiment of the present invention, these support means are in the form of a series of raised protrusions extending axially along the mid-line of each of the sides of divider as shown in FIGS. 2 and 3. Other embodiments of the divider may not require these protrusions due to the geometry of the divider. For example, the cross-shaped and starshaped dividers shown in FIGS. 13-14 and 16-17 are unlikely to allow collapse or substantial constriction of the lumens within the catheter tube.

Following completion of the insertion process, the 45 distal ends of the catheter tube and divider are removably attached to a distribution block of conventional design (not shown), which provides fluid communication for each of the separate lumens of the catheter with appropriate I.V. tubing and flow control devices for the respective fluids to be administered to the patient. Separate fluids and flow rates can be provided through each of the lumens of the catheter without mixing. The 50 volumetric flow of the respective fluids to be administered to the patient can be controlled either by flow control devices associated with the distribution block, by providing different cross-sectional areas for various lumens, or by using more than one of the lumens for a given fluid.

The expandable nature of the catheter tube allows the 55 cross-sectional area of each lumen to expand under the pressure of fluid flowing through the lumen, and to return to a substantially smaller cross-section when not in use. This feature is discussed in greater detail in U.S. Pat. No. 4,406,656.

FIGS. 9 and 9a show an alternative embodiment of the present invention in which the insertion needle 20 has a slit 22 extending axially along its entire length.

This insertion process entails first piercing wall of the blood vessel with the tip of the needle 20. The end of the catheter tube 10 inside the needle is carried into the interior of the blood vessel with the needle. The needle 20 is then retracted from within the vessel by sliding the needle back over the catheter tube 10, while leaving the end of the catheter tube in the blood vessel. The needle 20 is subsequently removed from the catheter tube 10 by slipping the tube through the slit 22 extending along the length of the needle. The width of this slit is such that the catheter tube 10 can be removed from inside the needle through the slit with minimal effort following insertion of the catheter tube into the blood vessel. However, the width of the slit must not be so large that the catheter tube falls out of the needle prior to completion of the insertion process. The optimal dimension for the width of the slit 22 will depend upon the elasticity of the catheter tube and the thickness of the catheter tube wall. In general, the width of the slit will be approximately twice the thickness of the catheter tube wall. A greater width may be necessary if the catheter tube is too inelastic to be readily collapsed to fit through the slit. On the other hand, a highly elastic catheter tube can be axially stretched to temporarily reduce its wall thickness, and thereby fit through a narrower slit in the needle. .

FIGS. 10 and 10a show another alternative embodiment of the present invention in which the catheter tube 10 is a sleeve that fits over the needle 20 prior to insertion. The needle inside the catheter tube is used to pierce the wall of the blood vessel. The beveled leading edge 16 of the catheter tube 10 allows the tube to be carried into the interior of the blood vessel with the needle. The needle is then withdrawn from inside the vessel and removed from the catheter tube 10. This is accomplished by pulling backward on the distal end of the needle which extends out of the distal end of the catheter tube, while holding the catheter tube 10 stationary so that the beveled end 16 of the tube remains in the blood vessel. Insertion of the divider into the catheter tube is then completed as discussed above. Thus, radial expansion of the catheter tube in this embodiment is required both for initial insertion of the needle 20 into the tube prior to insertion into the vessel, and for subsequent insertion of the divider into the catheter tube. The catheter tube 10 has a number of grooves 18 scored longitudinally along its exterior surface to facilitate this radial expansion of the catheter tube. If necessary, a separate elastic liner (not shown) located within the catheter tube can be employed to prevent rupture of the catheter tube in the event the grooves break apart during the insertion process.

FIG. 11 shows an alternative embodiment of the present invention in which a series of recessed grooves 39 extend along the interior surface of the catheter tube 10. The number and placement of the grooves correspond to the number and placement of the edges of the divider. During insertion of the divider into the tube, the edges or corners 32 of the divider are guided by these grooves. This eases insertion of the divider and helps insure a better seal between the edges of the divider and the catheter tube.

Although the divider is illustrated as being triangular in cross-section, any member of the general class of polygons can be utilized, such as a square, rectangle, diamond, pentagon, or hexagon. The divider can also be either hollow or solid. The divider can alternately have a Y-shaped, cross-shaped, or star-shaped cross section,

as shown in FIGS. 12, 13, and 16. In addition, the divider can either be solid, or have a hollow cross-section to provide an additional central lumen formed within the divider, as shown in FIGS. 14 and 17.

FIGS. 15a and 15b show a divider 30 in the form of a vertical bar that divides the catheter tube into two separate lumens. A series of raised protrusions 38 extend longitudinally along the midline of both faces of the divider to prevent collapse of the catheter tube against the sides of the divider.

FIG. 18 is a cross-sectional view of another alternative embodiment of the present invention in which recessed grooves 39 extend along the inside surface of the catheter tube to guide insertion of the divider as discussed above and shown in FIG. 11, and which also has a number of raised ridges 19 extending longitudinally along the exterior of the catheter tube. These raised ridges serve to reduce the surface area of the tube in contact with the insertion needle an with the wall of the blood vessel. This minimizes friction and reduces the amount of force necessary for insertion of the catheter tube.

The above disclosure sets forth a number of embodiments of the present invention. Other arrangements or embodiments, not precisely set forth, could be practiced under the teachings of the present invention and as set forth in the following claims.

We claim:

1. A multi-lumen catheter comprising:

- (a) a tube, said tube being radially expandable from a first state with a first inner radius, to a radially expanded second state with a second larger inner radius;
- (b) means for selectively expanding said tube from said first state to said radially expanded second state, said expanding means including an insertable divider having a radius greater than said first inner radius and substantially equal to said second inner radius, insertion of said divider thereby dividing said tube into a plurality of separate lumens.

2. The multi-lumen catheter of claim 1, further comprising a number of grooves extending along the interior of the tube to guide insertion of the divider through the length of the tube.

3. The multi-lumen catheter of claim 1 further comprising a number of grooves extending longitudinally along the exterior of the tube to facilitate radial expansion of the tube.

4. The multi-lumen catheter of claim 1 wherein the divider has a polygonal cross-section.

5. The multi-lumen catheter of claim 4 wherein the divider has a hollow triangular cross-section, with the area within the divider defining an additional lumen for the catheter.

6. The multi-lumen catheter of claim 1 further comprising a series of raised protrusions extending outward along the sides of the divider to prevent collapse of the tube against the divider.

7. A method of inserting a multi-lumen catheter into a blood vessel, comprising:

- (a) inserting one end of an expandable tube through an opening in the wall of the blood vessel; and
- (b) inserting a divider from the distal end of the tube through the length of the tube, thereby dividing the tube into a plurality of separate lumens and causing the tube to radially expand and substantially seal the opening between the outside of the tube and the opening in the wall of the blood vessel.

8. The method of claim 7, wherein the tube is inserted into the blood vessel by means of a hollow needle into which one end of the tube is inserted, and which is subsequently used to puncture the wall of the blood vessel.

9. The method of claim 7 wherein the divider has a polygonal cross-section.

10. The method of claim 7 wherein the divider has a cross-sectional configuration from the group consisting of a Y-shape, a cross, or a star having at least five points.

11. The method of claim 7 wherein divider has a triangular cross-section.

12. The method of claim 7 wherein the divider has a formed lumen extending axially within the divider.

13. A method of inserting a multi-lumen catheter into a blood vessel, comprising:

(a) inserting one end of an expandable tube through an opening in the wall of the blood vessel by means of a hollow needle into which one end of the tube is inserted, and which is subsequently used to puncture the wall of the blood vessel; and

(b) inserting a divider from the distal end of the tube through the length of the tube, thereby dividing the tube into a plurality of separate lumens.

14. A method of inserting a multi-lumen catheter into a blood vessel, comprising in the order of:

- (a) inserting one end of an expandable tube into a hollow needle;
- (b) inserting the needle through the wall of a blood vessel, so that the end of the tube inside the needle enters the blood vessel;
- (c) retracting the needle from the blood vessel and removing the needle from the tube, thereby leaving the end of the tube inside the blood vessel;
- (d) inserting a divider from the distal end of the tube through the length of the tube, thereby dividing the tube into a plurality of separate lumens.

15. The method of claim 14 wherein insertion of the divider into the tube causes the tube to radially expand, thereby substantially sealing the opening between the outside of the tube and the wall of the blood vessel.

16. The method of claim 14 wherein divider has a triangular cross-section.

17. The method of claim 16 wherein the divider has a hollow triangular cross-section, with the area within the divider defining a separate lumen.

18. The method of claim 14 wherein the needle has a slit extending its length through which the tube can be removed from inside the needle.

50 19. The method of claim 14 wherein the divider has a polygonal cross-section.

20. The method of claim 14 wherein the divider has a cross-sectional configuration from the group consisting of a Y-shape, a cross, or a star having at least five points.

21. The method of claim 14 wherein the divider has a formed lumen extending longitudinally with the divider.

22. The method of claim 14 wherein a number of grooves extending along the interior of the tube guide insertion of the divider through the length of the tube.

23. The method of claim 14 wherein a number of grooves extend longitudinally along the exterior of the tube to facilitate radial expansion of said tube as the divider is inserted.

24. The method of claim 14 wherein a series of raised protrusions extend outward from the divider to prevent collapse of the tube against the divider.

\* \* \* \* \*

# EXHIBIT C



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,312	12/30/2003	Jessica R. DesNoyer	50623.313	1694
7590 Cameron Kerrigan Squire, Sanders & Dempsey L.L.P. One Maritime Plaza, Suite 300 San Francisco, CA 94111	12/12/2007			
<b>FINAL OFFICE ACTION</b>				
RESPONSE DUE: <u>3/12/08</u>				
NTC of APPEAL DUE: <u>6/12/08</u>				
		EXAMINER		
		LAMB, BRENDA A		
		ART UNIT	PAPER NUMBER	
		1792		
		MAIL DATE	DELIVERY MODE	
		12/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DOCKETED: N/A  
\_\_\_\_\_  
DEC 17 2007  
BY: AV Attn: JL  
SQUIRE SANDERS & DEMPSEY

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/750,312	DESNOYER ET AL.	
	Examiner Brenda A. Lamb	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 September 2007.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-9,11,13,14 and 19-25 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4-9,11,13,14 and 19-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as obvious over Hattler et al 4,846,791 in view of Berg et al 5,674,208.

Hattler et al shows as depicted in Figures 1-3 stent and a stent mandrel support supporting the catheter or stent comprising: a first member (protrusions arranged at one end of the mandrel) to contact a first end of the stent; a second member (protrusions arranged at the opposite end of the mandrel) to contact a second end of the stent; and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member having at least three walls 34. Hattler et al shows the third member has a plurality of spikes and these spikes may contact the luminal surface. Hattler et al teaches the divider extends the entire length of the catheter

or stent (see column 4 lines 64-66). Although Hattler et al explicitly fails to teach the stents includes struts as set forth in claims 1 and 4-5, it would have obvious to support any known stent or catheter tube assembly including that disclosed by Berg et al catheter or stent assembly with metal braids within the catheter or stent assembly acting as a plurality of struts or structural elements used to strengthen a structure by resisting longitudinal compression on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar end results – a catheter assembly capable of being inserted into a blood vessel. Hattler et al mandrel is capable of supporting the catheter or stent during application of coating thereon and includes walls 34 which substantially prevent a coating from being formed on a portion of the luminal surface of the catheter or stent since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 2d 1647 (1987). With respect to claims 7-8, Hattler et al fails to teach the cross-section of the third member is within the scope of claims. Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped. Therefore, it would have been obvious to modify the mandrel in the Hattler et al stent and mandrel combination as set forth above by providing the third member with a shape within the scope of claims 7-8 since Hattler et

al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped obviously to provide greater support of the catheter or stent. With respect to claim 6, Hattler et al fails to teach that the spikes do not contact the luminal of the stent or catheter. Hattler et al teaches that the geometry of the divider may or may not require protrusions to provide support necessary to prevent collapse of the lumen within the catheter or stent. Therefore, it would have been obvious to modify the Hattler et al mandrel such that the spikes of the third member do not have to touch or contact the luminal of the stent as long as the number of protrusions on the third member are sufficient to prevent collapse of the luminal within the catheter or stent for the obvious reason of providing a plurality of discrete support points – enable one to provide continued support for the catheter despite wear of the one of the discrete protrusions.

Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as obvious over Hattler et al 4,846,791 in view of Tower 5,389,106.

Hattler et al shows as depicted in Figures 1-3 stent and a stent mandrel support supporting the catheter or stent comprising: a first member (protrusions arranged at one end of the mandrel) to contact a first end of the stent; a second member (protrusions arranged at the opposite end of the mandrel) to contact a second end of the stent; and a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member having at least least three walls 34 and these wall 34 are shaped and/or sized to substantially prevent a coating from being formed on a luminal surface of the catheter or stent. Hattler et al shows the third

member has a plurality of spikes and these spikes may contact the luminal surface. Hattler et al teaches the divider extends the entire length of the catheter or stent (see column 4 lines 64-66). Although Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claims 1 and 4-5, it would have obvious to support any known stent or catheter tube assembly including that disclosed by Tower catheter and stent assembly with wires within the wire frame within the catheter and stent assembly acting as a plurality of struts or structural elements used to strengthen a structure by resisting longitudinal compression on the Hattler et al mandrel especially since Hattler infers his mandrel body is capable of accepting different configurations of stent or catheter tubes as inferred by Hattler et al disclosure of the catheter tube or stent at column 5 lines 10-15 and column 6 lines 45-52 for the obvious reason to expect similar end results – a catheter assembly capable of being inserted into a blood vessel. Hattler et al mandrel is capable of supporting the catheter or stent during application of coating thereon and includes walls 34 which substantially prevent a coating from being formed on a portion of the luminal surface of the catheter or stent since it teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 2d 1647 (1987). With respect to claims 7-8, Hattler et al fails to teach the cross-section of the third member is within the scope of claims. Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped. Therefore, it would have been obvious

to modify the mandrel in the Hattler et al stent and mandrel combination as set forth above by providing the third member with a shape within the scope of claims 7-8 since Hattler et al teaches the third member can have shapes other than triangular such as cross-shaped or star-shaped obviously to provide greater support of the catheter or stent. With respect to claim 6, Hattler et al fails to teach that the spikes do not contact the luminal of the stent or catheter. Hattler et al teaches that the geometry of the divider may or may not require protrusions to provide support necessary to prevent collapse of the lumen within the catheter or stent. Therefore it would have been obvious to modify the Hattler et al mandrel such that the spikes of the third member do not have to touch or contact the luminal of the stent as long as the number of protrusions on the third member are sufficient to prevent collapse of the luminal within the Tower catheter and stent assembly for the obvious reason of providing a plurality of discrete support points – enable one to provide continued support for the catheter despite wear of the one of the discrete protrusions.

Claims 9,11,13-14 and 19-25 are rejected under 35 U.S.C. 103(a) as obvious over Hattler et al 4,846,791 in view of Rosenbluth 4,762,128 and Applicant's Admitted Prior Art (see pages 1-2 and Figure 1 of the originally filed specification).

Hattler et al teaches in drawings which include Figures 12-13 a mandrel assembly comprising: a member to penetrate at least partially into a longitudinal bore of a hollow cylindrical member, the member including outwardly projecting integral walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle. Hattler et al teaches at column 5 lines 10-15 that

the catheter tube supported on the mandrel is radially expandable. Hattler et al explicitly fails to teach the mandrel assembly in combination with a stent including a plurality of struts having abluminal and luminal surfaces in fluid communication through at least a pair of plurality of struts as set forth in newly amended claim 23. However, Rosenbluth teaches at column 10 line 53 to column 11 line 2 coating an expandable stent mounted on a mandrel and catheter assembly prior to its use. Therefore, it would have been obvious to arrange any conventional stent such as one taught by Applicant's Admitted Prior Art which has struts and structure within the scope of the claim on the Hattler et al mandrel and catheter assembly such that the member of the mandrel penetrates the longitudinal bore of the stent since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly to enable one to coat the stent prior to its use. Thus claim 23 is obvious over the above cited references. With respect to claim 19, Hattler et al teaches as depicted in the drawings which includes Figure 16 the design of a mandrel and catheter assembly comprising: a member to penetrate at least partially into a longitudinal bore of a hollow cylindrical member, the member including 6 sides and each side wall surface is non-parallel with its neighboring side wall surface. Hattler et al explicitly fails to teach the stents includes struts and have structure within the scope of newly amended claim 19. However, it would have been obvious to arrange any conventional stent such as one taught by Applicant's Admitted Prior Art which has struts and structure within the scope of the claim on the Hattler et al mandrel and catheter assembly such that the member of the mandrel penetrates the longitudinal bore of the stent since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly

to enable one to coat the stent prior to its use. Thus claim 19 is obvious over the above cited references. With respect to claims 9, 11 and 13-14, Rosenbluth teaches the supporting the stent on a mandrel assembly and the length of the mandrel assembly relative to the length of the stent is within the scope of the claim. Hattler et al shows the mandrel is comprised of a member including integrally formed walls that have a shape and length within the scope of the claims (see Figures 12-13 and 16). Hattler et al teaches at column 5 lines 10-15 that the catheter tube or stent supported on the mandrel is radially expandable. Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claims 9,11 and 13-14. However, it would have obvious to arrange any conventional stent including that disclosed by Applicant's Admitted Prior Art on the Hattler et al mandrel and catheter assembly especially since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly to enable one to coat the stent prior to its use. With respect to claims 24-25, Hattler et al shows as depicted in Figures 1-3 a mandrel and catheter assembly comprising a member having a first end, a second end and at least three sides or walls 34 which extend between the first and second end. Rosenbluth teaches the supporting a stent on a mandrel and catheter assembly. Rosenbluth shows in his Figures the length of the mandrel assembly relative to the length of the stent is within the scope of the claim. Hattler et al explicitly fails to teach the stents includes struts as set forth in newly amended claims 24-25. However, it would have obvious to arrange any conventional stent including that disclosed by Applicant's Admitted Prior Art on the Hattler et al mandrel and catheter

assembly especially since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly to enable one to coat the stent prior to its use.

Applicant's arguments filed 9/25/2007 have been fully considered but they are not persuasive.

Applicant's argument that the recitation that the third member substantially prevents coating from being formed on the luminal surface of the stent is a structural limitation and is more than intended end use is found to be non-persuasive. The examiner maintains that Hattler et al apparatus is capable of supporting the catheter or stent during application of coating thereon such that the third member substantially prevents coating from being formed on at least a portion of the luminal surface of the stent via a portion of the third member which contacts the luminal of the stent, the outer corners 32 of the third member, and especially since Hattler et al teaches every positively claimed element of the apparatus. Note it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ 2d 1647 (1987).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda A. Lamb whose telephone number is (571) 272-1231. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday with alternate Wednesdays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton, can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number:  
10/750,312  
Art Unit: 1792

Page 11

*Brenda Adeb-Lamb*  
Brenda A Lamb  
Examiner  
Art Unit 1734

<b>Notice of References Cited</b>		Application/Control No.	Applicant(s)/Patent Under Reexamination DESNOYER ET AL.	
		10/750,312	Examiner Brenda A. Lamb	Art Unit 1792      Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-4,762,128	08-1988	Rosenbluth, Robert F.	606/192
	B US-			
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			

**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

**NON-PATENT DOCUMENTS**

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U
	V
	W
	X

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

# EXHIBIT D



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,312	12/30/2003	Jessica R. DesNoyer	50623.313	1694
7590	03/06/2008			
Cameron Kerrigan Squire, Sanders & Dempsey L.L.P. One Maritime Plaza, Suite 300 San Francisco, CA 94111			EXAMINER	
			LAMB, BRENDA A	
			ART UNIT	PAPER NUMBER
			1792	
			MAIL DATE	DELIVERY MODE
			03/06/2008	PAPER

**ADVISORY ACTION**

RESPONSE DUE: N /   

4 MONTH DATE:    /   

5 MONTH DATE:    / A

DROP DEAD DATE:    /   

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DOCKETED: Notice of Appeal filed 3/12/08  
Appeal Brief due: 5/12/08  
MAR 3 2008

BY: tjc Atty. JR  
SQUIRE, SANDERS & DEMPSEY

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	10/750,312	DESNOYER ET AL.	
	Examiner Brenda A. Lamb	Art Unit 1792	
<i>--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--</i>			
<b>THE REPLY FILED 12 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.</b>			
<p>1. <input checked="" type="checkbox"/> The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:</p> <p>a) <input type="checkbox"/> The period for reply expires _____ months from the mailing date of the final rejection.</p> <p>b) <input checked="" type="checkbox"/> The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.</p> <p>Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).</p>			
<p>Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p>			
<p><b>NOTICE OF APPEAL</b></p> <p>2. <input type="checkbox"/> The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).</p>			
<p><b>AMENDMENTS</b></p> <p>3. <input type="checkbox"/> The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because</p> <p>(a) <input type="checkbox"/> They raise new issues that would require further consideration and/or search (see NOTE below);</p> <p>(b) <input type="checkbox"/> They raise the issue of new matter (see NOTE below);</p> <p>(c) <input type="checkbox"/> They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or</p> <p>(d) <input type="checkbox"/> They present additional claims without canceling a corresponding number of finally rejected claims.</p> <p>NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).</p>			
<p>4. <input type="checkbox"/> The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).</p> <p>5. <input type="checkbox"/> Applicant's reply has overcome the following rejection(s): _____.</p> <p>6. <input type="checkbox"/> Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).</p> <p>7. <input type="checkbox"/> For purposes of appeal, the proposed amendment(s): a) <input type="checkbox"/> will not be entered, or b) <input type="checkbox"/> will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.</p> <p>The status of the claim(s) is (or will be) as follows:</p> <p>Claim(s) allowed: _____.</p> <p>Claim(s) objected to: _____.</p> <p>Claim(s) rejected: _____.</p> <p>Claim(s) withdrawn from consideration: _____.</p>			
<p><b>AFFIDAVIT OR OTHER EVIDENCE</b></p> <p>8. <input type="checkbox"/> The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).</p> <p>9. <input type="checkbox"/> The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).</p> <p>10. <input type="checkbox"/> The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.</p>			
<p><b>REQUEST FOR RECONSIDERATION/OTHER</b></p> <p>11. <input checked="" type="checkbox"/> The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  <u>See Continuation Sheet</u></p> <p>12. <input type="checkbox"/> Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.</p> <p>13. <input type="checkbox"/> Other: _____.</p>			
<i>/Brenda A Lamb/ Primary Examiner, Art Unit 1792</i>			

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's argument that it would have not been obvious to replace tube 10 with a tube having an embedded stent structure is found to be non-persuasive. As discussed in the final office action, it would have been obvious to arrange any conventional stent such as one taught by Applicant's Admitted Prior Art which has struts and structure within the scope of the claim on the Hattler et al mandrel and catheter assembly such that the member of the mandrel penetrates the longitudinal bore of the stent since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly to enable one to coat the stent prior to its use. In other words with respect to claims 9,11,13-14 and 19-25, one is not suggesting replacing the Hattler et al tube 10 with a stent comprising struts having abluminal surfaces and luminal surfaces in fluid communication through a pair of struts rather placing a conventional stent such as one taught by Applicant's Admitted Prior Art which has struts and structure within the scope of the claim on the Hattler et al mandrel and catheter assembly such that the member of the mandrel penetrates the longitudinal bore of the stent since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly to enable one to coat the stent prior to its use (see column 10 line 53 to column 11 line 2).

Applicant's alleges that if one were to replace Hattler et al tube 10 with a stent then the stent would not be able to follow the natural curvature of a blood vessel without causing damage because a stent lacks this kind of flexibility is found to be non-persuasive since it is not commensurate in scope with claim language with claim language silent as to movement through a blood vessel or vein and ,in any event if claims were amended so, Applicant's Admitted Prior Art stent is disclosed as being insertable in blood vessels and therefore obviously has the desired flexibility.

Applicant's argument that the divider of Hattler et al needs to contact the walls of the catheter or stent and therefore the recitation in dependent claim 6 that the plurality of spikes do not contact the luminal surface of the stent defines over the art of record is found to be non-persuasive. Hattler et al teaches that the geometry of the divider may or may not require protrusions to provide support necessary to prevent collapse of the lumen within the catheter or stent (see column 5 lines 31-44). Therefore, it would have been obvious to modify the Hattler et al mandrel such that the spikes of the third member do not have to touch or contact the luminal of the stent as long as the number of protrusions on the third member are sufficient to prevent collapse of the luminal within the catheter or stent for the obvious reason of providing a plurality of discrete support points – enable one to provide continued support for the catheter despite wear of the one of the discrete protrusions.

All arguments set forth in the instant after-final amendment are well taken, however, rejections of the claims under the prior art is sustained for the reasons set forth in the final office action.

# EXHIBIT E

# United States Patent [19]

Rosenbluth

[11] Patent Number: 4,762,128

[45] Date of Patent: Aug. 9, 1988

[54] METHOD AND APPARATUS FOR  
TREATING HYPERSTROPHY OF THE  
PROSTATE GLAND

[75] Inventor: Robert F. Rosenbluth, Laguna  
Niguel, Calif.

[73] Assignee: Advanced Surgical Intervention, Inc.,  
San Clemente, Calif.

[21] Appl. No.: 939,754

[22] Filed: Dec. 9, 1986

[51] Int. Cl. 4 A61M 25/00; A61M 29/02

[52] U.S. Cl. 128/343; 128/344;  
604/96

[58] Field of Search 604/96-103;  
128/325, 341-345, 348.1

## [56] References Cited

### U.S. PATENT DOCUMENTS

4,560,374 12/1985 Hammerslag 128/344 X  
4,580,568 4/1986 Gianturco 604/96 X  
4,641,653 2/1987 Rockey 128/344  
4,649,922 3/1987 Wiktor 128/344  
4,655,771 4/1987 Wallsten 128/343 X  
4,660,560 4/1987 Klein 128/344

### FOREIGN PATENT DOCUMENTS

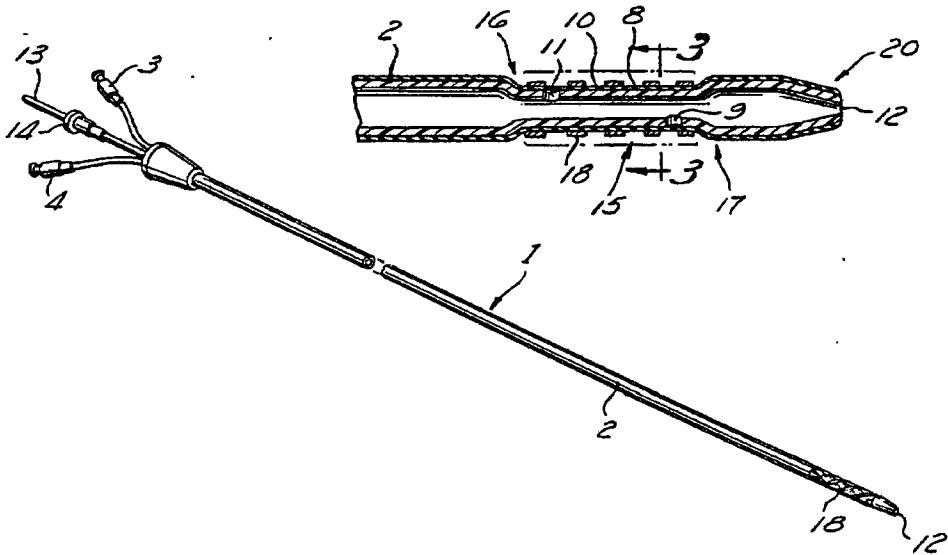
1205743 9/1970 United Kingdom 128/343

Primary Examiner—Dalton L. Truluck  
Attorney, Agent, or Firm—Knobbe, Martens, Olson &  
Bear

## [57] ABSTRACT

Disclosed is a method and apparatus for treatment of hypertrophy of the prostate gland. The apparatus comprises an expansion catheter having an expandable tubular stent associated therewith, adapted for transurethral insertion via the external opening of the urethra and placement within a stenotic region of the urethral lumen caused by a hypertrophied prostate gland. Force exerted by the expansion catheter upon the tubular expandable stent causes an opening of the lumen within the prostatic urethra. Removal of the expansion catheter, leaving in place the expanded tubular stent, ensures long-term patency of the urethral lumen. Also disclosed is an apparatus for reducing in diameter and thereafter removing a previously implanted and expanded tubular stent made and inserted in accordance with the present invention.

28 Claims, 4 Drawing Sheets



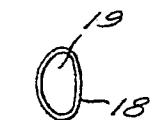
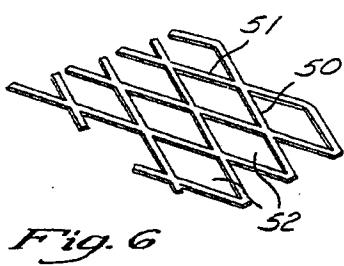
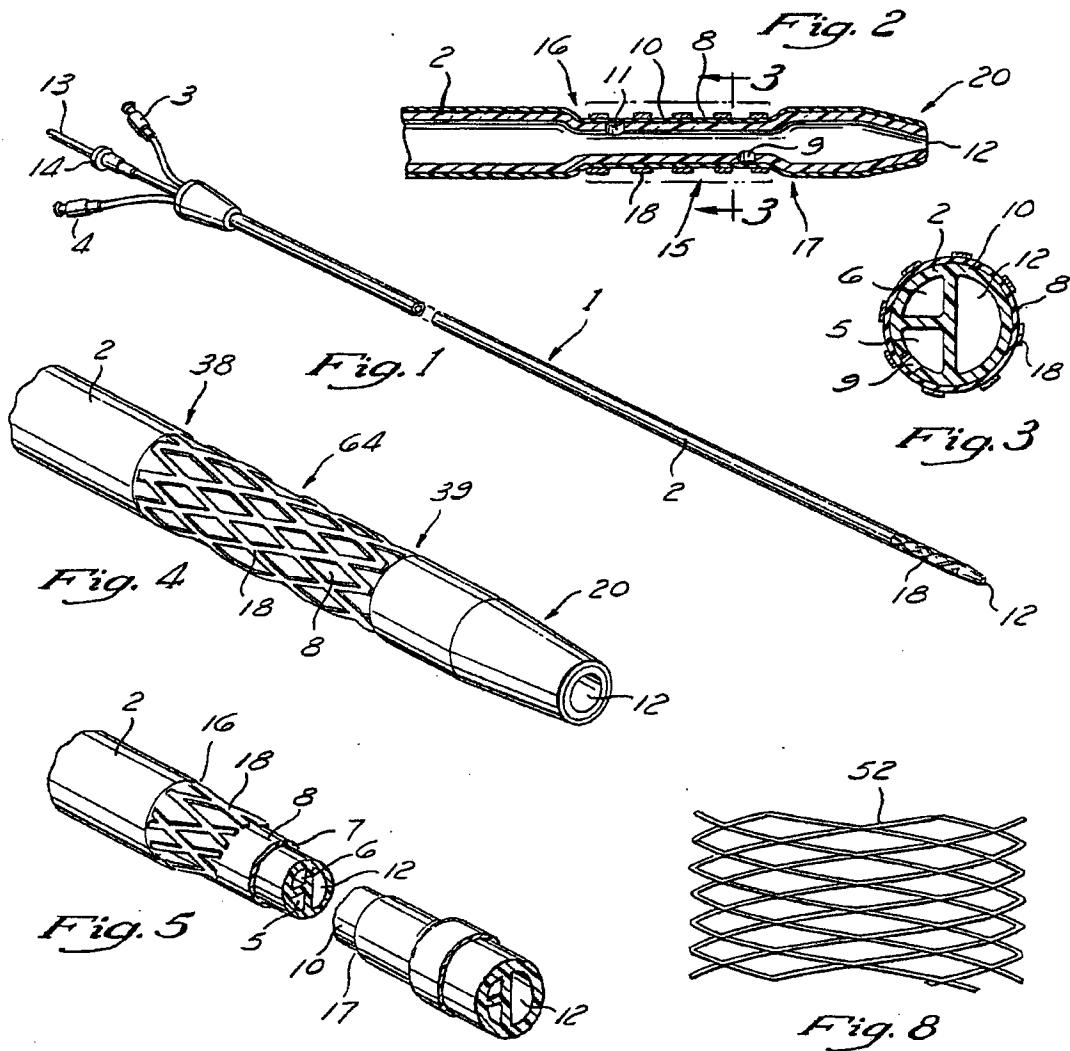
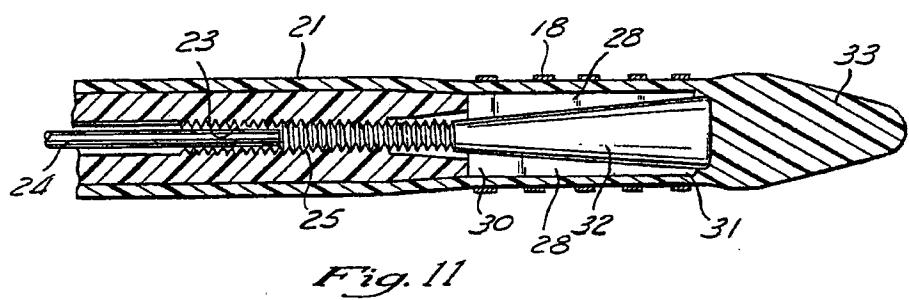
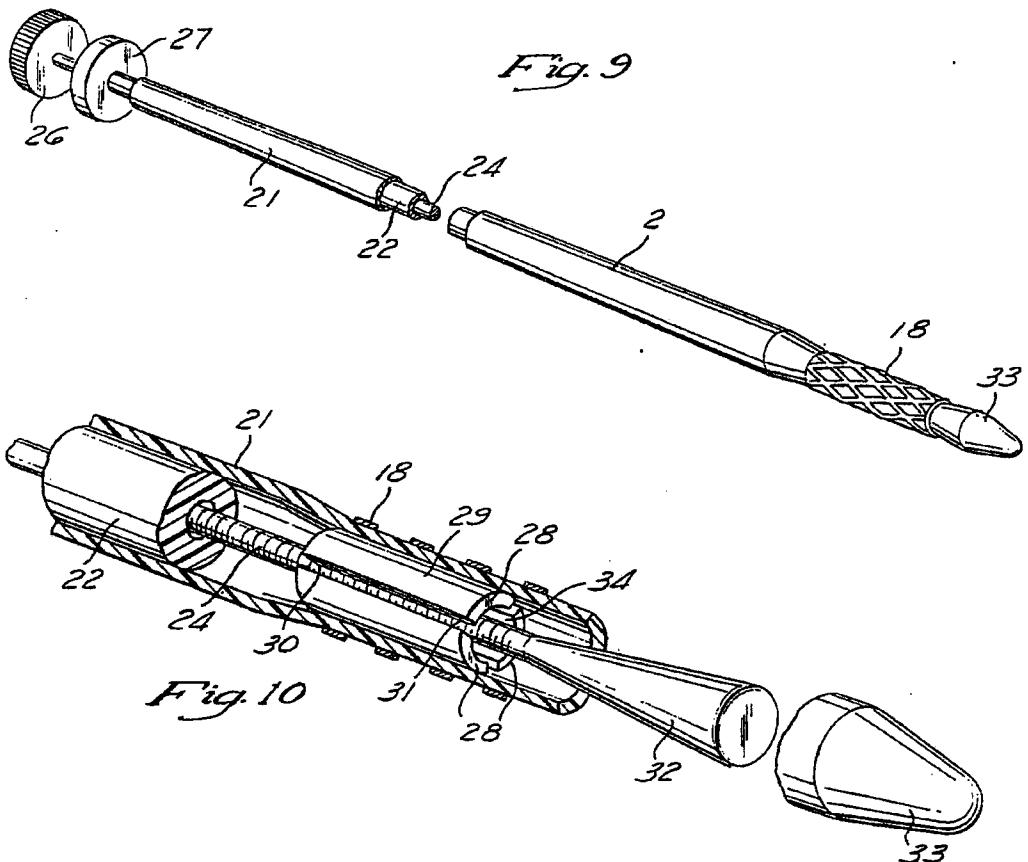


Fig. 7



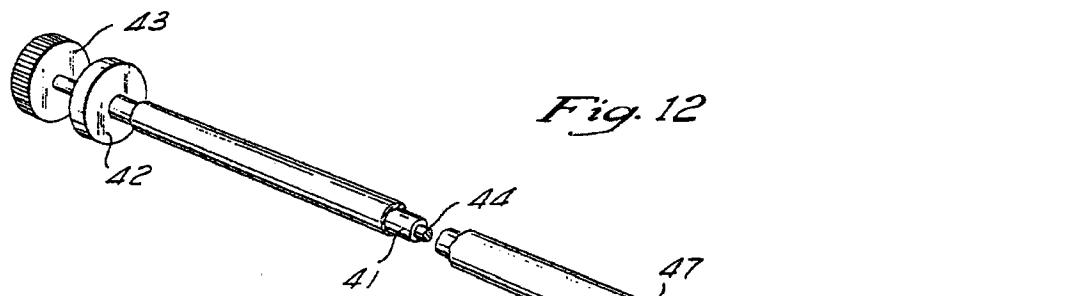


Fig. 12

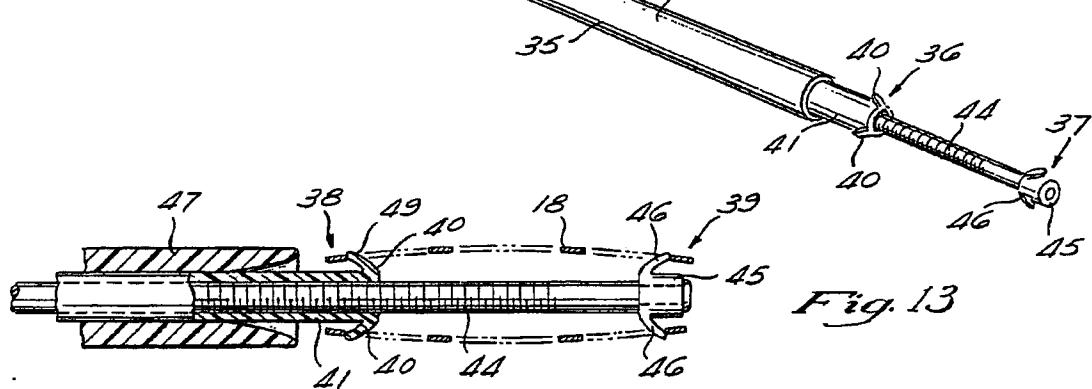


Fig. 13

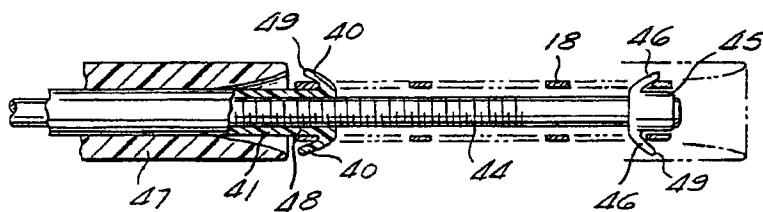


Fig. 14

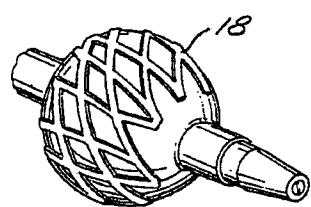
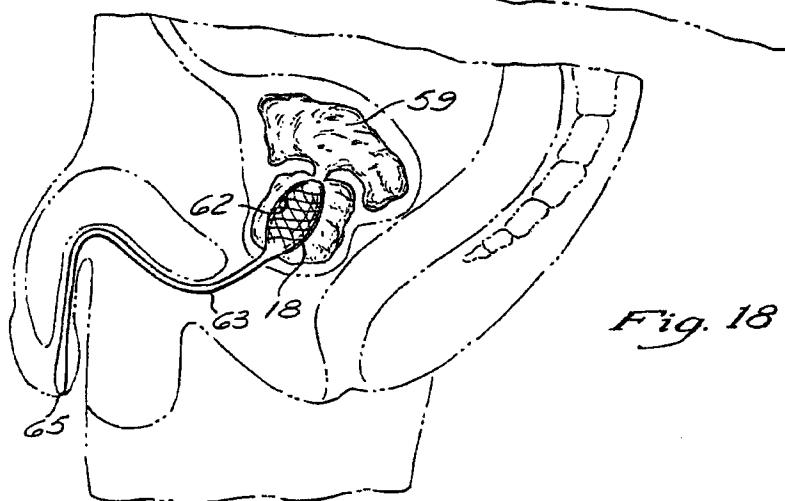
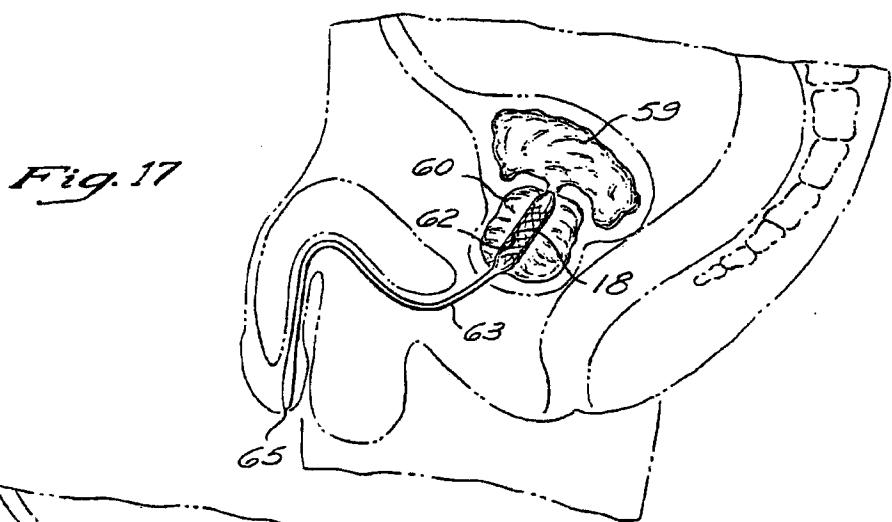
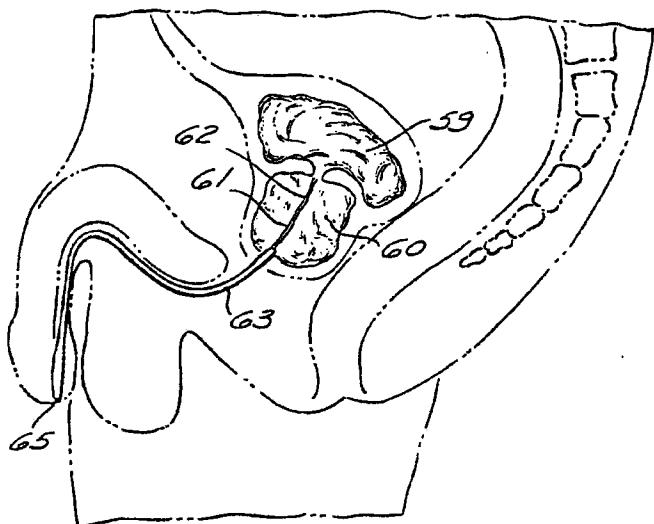


Fig. 15



METHOD AND APPARATUS FOR TREATING  
HYPERTROPHY OF THE PROSTATE GLAND

BACKGROUND OF THE INVENTION

The surgical treatment of hypertrophy of the prostate gland has been a routine procedure in the operating room for many years. One method of surgical treatment is open prostatectomy whereby an incision is made to expose the enlarged prostate gland and the hypertrophied tissue is removed under direct vision. Another method, which has gained increasing usage in recent years, is transurethral resection. In this procedure, an instrument called a resectoscope is placed into the external opening of the urethra and an electrosurgical loop is used to carve away sections of the prostate gland from within the prostatic urethra under endoscopic vision. For an interesting historical survey of prostate surgery see the book "Benign Prostatic Hypertrophy" edited by Frank Hinman, M.D. and particularly the chapter entitled "Prostatectomy, Past and Present" by Geoffrey D. Chisholm, M.D.

The technique of transurethral resection offers many benefits to the patient as compared to open prostatectomy. Using this technique the trained urologist can remove the hypertrophied prostate with less discomfort, a shorter hospital stay, and lower rates of mortality and morbidity. Over 333,000 patients underwent this procedure in the United States in 1985, with an average length of stay in the hospital of six days.

Notwithstanding the significant improvement in patient care resulting from the widespread application of transurethral resection, there remains a need for a less invasive method of treating the symptoms of prostate disease. Various complications including impotence, incontinence, bleeding, infection, residual urethral obstruction, urethral stricture, and retrograde ejaculation may affect the patient following transurethral resection. A less invasive procedure which would reduce or eliminate the occurrence of these complications and reduce the hospital stay and resulting costs would be of significant value.

One of the earliest applied methods of relieving the acute urinary retention symptomatic of prostate disease was the placement of a catheter through the external urethra opening into the bladder thereby allowing the outflow of urine from the bladder by way of the catheter lumen. These urinary catheters typically employ a balloon at the tip which, when inflated, prevent the expulsion of the catheter from the body. Although this method is effective in achieving urinary outflow, it is generally unacceptable as a long term treatment due to problems of infection, interference with sexual activity, and maintenance and change of catheters.

The use of dilating bougies and sounds for mechanical dilation of the prostatic urethra has been attempted without success in the treatment of prostatic hypertrophy. The fibrous tissue of the prostate gland rebounds after dilation, resulting in only a temporary reduction of urethral constriction. A method of treating prostate disease involving the application of balloon dilatation in a similar manner as in percutaneous transluminal angioplasty of arterial occlusions has been proposed in an article in the September 1984 issue of *Radiology*, page 655 entitled "Prostatic Hyperplasia: Radiological Intervention" by H. Joachim Burhenne, M.D., et al. This method of prostate dilatation can be expected to have only a short term alleviation of urinary retention as the

fibrous and resilient hypertrophied prostate gland will in a relatively short period of time cause the constriction of the prostatic urethra to recur. Also in the angioplasty arts, Palmaz, et al. have described the percutaneous, sheathed insertion of an expandable endoprosthesis into various major arteries of dogs in the article "Expandable Intraluminal Graft: A Preliminary Study" in the July 1985 issue of *Radiology* at page 73.

In contrast to the failure of dilation means to achieve lasting relief of the symptoms of prostatic hyperplasia, the use of bougie, sound, and balloon dilation has achieved moderate success in the treatment of ureteral strictures and non-prostatic urethral strictures. See, for example, the abstract entitled "Self Intermittent Dilatation Program via Coaxial Balloon Urethral Dilator" by J. D. Giesen et al. published in the April, 1985 issue of the *Journal of Urology*. The contrasting lack of success achieved by dilation in the prostatic urethra is believed to be a function of the differing etiology of the disease. Strictures in the urethra outside of the prostate region are generally due to pathology of the wall and lining of the urethra. Dilation of the urethral wall, in these strictures, causes an enlargement of the urethral lumen through deformation of the urethral wall and lining. In contrast, urethral stenosis resulting from prostatic hypertrophy, is a disease of the enlarged, fibrous, and resilient tissue of the prostate gland. Deformation of the urethral wall will have no lasting effect on relieving the stenosis as the cause of the stenosis is pressure exerted by the hypertrophied prostate gland which, due to its resilient fibrous structure and large bulk, will tend to rebound after temporary compression.

It is important that a method for prostate dilatation, in order to be effective, incorporate means of maintaining the patency of the urethral lumen. Without such means, the patient would be subject to periodically repeated procedures in order to maintain urinary flow.

SUMMARY OF THE INVENTION

The present invention provides a method of relieving the urinary retention symptomatic of hypertrophy of the prostate gland, which requires little or no hospitalization, and which is unattended by the adverse side effects associated with transurethral resection and other surgical techniques. In addition, the present invention provides a method for dilatation of the prostatic urethra which will insure long term patency of the urethral lumen.

Thus, there has been provided in accordance with one aspect of the present invention a method for treating hypertrophy of the prostate gland, which comprises the steps of transurethrally inserting and positioning a dilatation means having an expandable tubular stent associated therewith within a restricted portion of the urethra and dilating the stent with said dilatation means to a predetermined maximum external diameter and configuration. The exterior configuration of the apparatus of the present invention enables insertion thereof without the use of a sheath, and with the tubular stent substantially totally exposed to the wall of the urethra. Preferably, dilation of the stent and consequent dilation of the surrounding restricted portion of the urethral lumen is effected at least to the extent that it eliminates the stenosis. Thereafter, the dilatation means is returned to its undilated state and withdrawn through the lumen of the dilated tubular stent, leaving the dilated tubular stent within the previously restricted portion of the

urethra, thereby restoring patency to the prostatic urethral lumen. Visualization of the placement step may be accomplished through the use of a radiopaque dye, in accordance with known techniques. Radiopaque markers on the catheter and radiopacity of the graft are also used to make the devices radiographically visible.

An additional aspect of the method of the present invention comprises the steps of reinserting a dilatation apparatus into the external opening of the urethra, positioning the dilation apparatus coaxially within a previously positioned and dilated tubular stent, expanding the dilatation apparatus, and thereafter reducing the diameter of and removing the dilatation apparatus leaving the expanded tubular stent within the urethra. Accordingly, an expandable tubular stent inserted in accordance with the method of the present invention may, at a later time, be further dilated or redilated.

Still a further aspect of the method of the present invention provides for the removal of a previously positioned stent. Removal is accomplished by transurethral insertion of a removal instrument comprising a first and second attachment means wherein the attachment means are axially spaced apart and are adapted to releasably engage the corresponding first and second axial ends of the stent. Once engaged, a force is applied to cause an axial elongation of the stent, and consequent reduction in diameter. Thereafter, the instrument and the radially reduced stent attached thereto may be removed.

In accordance with another aspect of the present invention there has been provided an apparatus for the treatment of prostatic hypertrophy comprising an expansion catheter having an expandable tubular stent associated therewith. The catheter comprises a radially expandable region near the distal end thereof which, in its unexpanded state, has an outer diameter that is smaller than the outer diameter of the adjacent region of the catheter. Thus, the collapsed expandable region forms the bottom of an annular depression about the catheter.

The stent is removably, coaxially disposed about the expandable region of the catheter and within the annular depression formed therearound, and is controllably radially outwardly expandable in response to pressure from the expandable region of the catheter. When the stent is coaxially disposed about the expandable region of the catheter, and in an unexpanded state, the outer diameter of the unexpanded stent is approximately the same as or less than the outer diameter of the adjacent region of the catheter. Preferably, the distal end of the catheter comprises a flexible, resilient material in a shape to facilitate insertion into and negotiation of a collapsed lumen with minimal trauma to the lining thereof.

A further aspect of the present invention provides a radially outwardly expandable tubular stent for restoring patency to a collapsed portion of the urethral lumen. Preferably, the stent comprises a material that is compatible with the urethral environment, and is capable of remaining in its expanded state following removal of the expansion catheter described above, thereby holding open the lumen of the urethra against a restricting pressure, such as that exerted by a hypertrophied prostate gland. The cross section of the expanded stent may be circular, or may also be a non-circular configuration which more closely corresponds to the shape of the normal lumen within the urethra. One embodiment of the stent in its expanded state comprises a substantially

uniform cross-sectional area throughout its axial length. In another embodiment, the stent comprises a smaller cross-sectional area at its axial ends than in the central region thereof. In addition, the axial end regions of the stent may comprise a flexible material, or may taper in a radial inward direction thereby easing the transition from the lumen of the stent to the lumen of the urethra.

Further objects, features and advantages of the present invention will become apparent from the detailed description of preferred embodiments which follows, when considered together with the attached Figures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an apparatus according to the present invention, with the tubular stent in an unexpanded state.

FIG. 2 is a schematic detail view of the distal end of an apparatus according to the present invention, with the tubular stent in an unexpanded state.

FIG. 3 is a cross-sectional view taken along the line 3-3 in FIG. 2.

FIG. 4 is an enlarged, perspective view of the distal end of an apparatus in accordance with the present invention.

FIG. 5 is a perspective, sectional view of the distal end of an apparatus in accordance with the present invention.

FIG. 6 illustrates one embodiment of the side wall pattern of a tubular stent according to the present invention.

FIG. 7 is a cross-sectional view of a tubular stent of the present invention expanded to a configuration having a non-circular cross section.

FIG. 8 illustrates a modification of the side wall pattern illustrated in FIG. 6.

FIG. 9 is a perspective view of another embodiment of an expansion catheter according to the present invention.

FIG. 10 is a detailed perspective view of the distal end of the apparatus in FIG. 9.

FIG. 11 is an elevational, sectional view of the apparatus in FIG. 10.

FIG. 12 is a perspective view of a removal apparatus according to the present invention.

FIG. 13 is a sectional view of the removal apparatus of FIG. 12, engaging an expanded tubular stent.

FIG. 14 is a sectional view of the removal apparatus of FIG. 13, following axial elongation of the tubular stent.

FIG. 15 is a simplified schematic view of the apparatus of the present invention shown in FIG. 1, with a generally convex balloon and corresponding tubular stent illustrated in the expanded state.

FIG. 16 is a simplified sectional view of the region of the male pelvis showing the urethra, prostate gland and bladder.

FIG. 17 is the sectional view of FIG. 16, illustrating an expanded stent of the present invention within the prostatic urethra.

FIG. 18 is the sectional view of FIG. 16, illustrating another embodiment of the expanded stent of the present invention within the prostatic urethra.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

## Expansion Catheter of FIGS. 1-5

Referring to FIGS. 1-5 there is illustrated an expansion catheter 1 according to the present invention, which in this embodiment comprises a balloon catheter, having an axially elongate, catheter shaft 2. The proximal, control end of the catheter 1 may be equipped as would be the control end of known angioplasty balloon catheters such as that disclosed in U.S. Pat. No. 4,573,470 to Samson, et al. The embodiment of the present invention illustrated in FIG. 1 has an inflation port 3 and optimally a distinct vent port 4, each in fluid communication, respectively, with an inflation lumen 5 and a vent lumen 6 (illustrated in FIG. 3) extending axially through the catheter. Inflation lumen 5 is in fluid communication at the distal end thereof with the interior 7 of an expandable balloon 8 by means of at least one inflation duct 9 through the wall 10 of the catheter proximal lumen 5 and adjacent the interior surface of balloon 8. Similarly, vent lumen 6 is in fluid communication with the interior 7 of balloon 8 by means of at least one vent duct 11 proximal to inflation duct 9. At the commencement of filling the balloon, any air in the lumen 5, 6 or in the interior 7 of balloon 8 will be chased out of vent port 4, which may then be sealed by a stopcock or other means (not illustrated).

A third lumen 12 may be provided for receiving a radiopaque dye introduced by way of dye port 14 at the proximal end thereof. A guidewire 13 may also be inserted through dye port 14 and lumen 12.

Near the distal, functional end of the catheter, a region 10 of the catheter shaft 2 is reduced in diameter to provide an annular depression 15 defined axially by a proximal annular shoulder 16 and a distal annular shoulder 17 on catheter shaft 2. The axial length of the annular depression preferably corresponds to the desired length of a stent 18 to be inserted in a given application. Referring to FIG. 3, there is disposed concentrically about the reduced catheter wall 10 and at the radially inward most region of the annular depression 15, annular inflatable balloon 8 in fluid communication with said inflation lumen 5 by way of duct 9. An expandable, tubular stent 18 having a central lumen 19 therethrough (illustrated in FIG. 7), discussed infra, is coaxially disposed about the balloon 8.

The expansion catheter 1 of the present invention is designed so that the outer, substantially cylindrical profile of the catheter is uninterrupted by the presence of the expandable stent 18, in its unexpanded state. Accordingly, in the case of a balloon catheter, the outer diameter of the collapsed balloon 8 is smaller than the outer diameter of shoulders 16, 17 of the adjacent catheter shaft 2, so that the collapsed balloon 8 only partially fills the annular depression 15 formed between the annular shoulders 16, 17, in the radial direction. The unexpanded stent 18 is disposed coaxially about balloon 8 and between shoulders 16 and 17 such that the stent 18 and adjacent catheter shaft 2 comprise a substantially cylindrical configuration. This configuration enables insertion of the apparatus without the need for a sheath.

The material of the balloon 8 is in the form of a tubular sleeve which extends the length of the catheter 1 and is adhered to the wall of the catheter shaft 2 proximal to shoulder 16 and distal to shoulder 17 but not in the

region 15 where it forms balloon 8 and is permitted to expand.

Introduction of pressurized fluid into the interior 7 of balloon 8 by way of inflation lumen 5 causes radial expansion of the balloon 8, which in turn causes a radial expansion of the stent 18 disposed concentrically therearound. Once expanded by inflating the balloon 8, the inner diameter of the central lumen 19 through expanded stent 18 is greater than the outer diameter of the catheter shaft 2 in the region between the annular depression 15 and the distal end of the catheter 1, including shoulder 17. Thus, following deflation of the balloon 8, the catheter 1 may be withdrawn through the central lumen 19 of stent 18 leaving the expanded stent 18 in place within the prostatic urethra, as will be detailed infra in connection with the method of the present invention.

The outer diameter of the catheter is preferably minimized, to facilitate insertion and to avoid side effects and complications resulting from stretching of the urethra. There may be provided in accordance with the present invention a graduated set of graft-catheter systems with different sizes to suit individual patient requirements.

The catheter may be provided with a flexible, resilient catheter tip 20 at the distal end thereof. The tip 20 is preferably formed with a tapered or rounded configuration to minimize damage to the urethral lining and further to ease in insertion of the catheter into the collapsed lumen of the urethra.

## Expansion Catheter of FIGS. 9-11

Another embodiment of an expansion catheter according to the present invention is illustrated in FIGS. 9-11. In this embodiment, there is provided an elongate catheter shaft 2 having an elastic sheath 21 disposed therearound. The shaft comprises an elongate sleeve 22 having a female thread 23 on the interior thereof. Rotatably positioned within the sleeve 22 is an elongate shaft 24 having a male thread 25 for engaging the female thread 23 on sleeve 22. The threaded region, illustrated in FIG. 11 near the distal ends of shaft 24 and sleeve 22, extends in an axial direction for a sufficient distance to permit the expansion member 32 to be fully drawn into the conical space 34 as will become apparent. In the illustrated embodiment, a first knob 26 is rigidly secured to the proximal end of shaft 24, and a second knob 27 is secured to the proximal end of sleeve 22.

A plurality of axially oriented floating segments or tines 28 are movably disposed distal to the end of sleeve 22. The exterior surfaces 29 of the tines 28 are held in place by the elastic sheath 21 and cooperate to form a generally cylindrical exterior profile, for receiving an unexpanded tubular stent 18. The radial thickness of the tines 28 tapers from the thickest dimension near the proximal end 30 of tine 28 to the thinnest dimension near the distal end 31 of tine 28, thereby defining a roughly cone-shaped interior space 34.

A cone-shaped expansion member 32 is attached by its pointed end to elongate shaft 24. Rotation of knob 26 in a first direction relative to knob 27 draws elongate shaft 24 axially in a proximal direction, moving expansion member 32 into the cone-shaped space 34 formed by the tines 28. Further rotation of knob 26 in a first direction relative to knob 27 results in expansion member 32 effecting a radial outward expansion of tines 28, which in turn causes a radial outward expansion of the expandable stent 18. Rotating the knob 26 in the reverse

relative direction causes expansion member 32 to back out of the space 34. The resilient nature of the elastic sheath 21 causes tines 28 to return back to their unexpanded configuration, when permitted by movement of member 32 in a distal direction. The tubular elastic sheath 21 extends beyond the end of expansion member 32 at which point it merges with an integrally formed blunt end 33. As illustrated in FIG. 11, the outer diameter of blunt end 33 and of the sheath 21 proximal to stent 18 are slightly enlarged so that the exterior configuration of the expansion catheter, with the stent mounted thereon is substantially uniform and generally smooth along its axial length.

#### Stent Removal Apparatus

Another aspect of the present invention provides an apparatus for removing a previously positioned and expanded stent, under direct endoscopic vision. Referring to FIGS. 12-14, the apparatus comprises a catheter shaft 35, having proximal and distal attachment means 36, 37 attached thereto and adapted to engage the corresponding proximal and distal ends 38, 39 of the implanted stent. The attachment means are capable of movement, relative to each other, along the axial direction of the removal instrument.

In the illustrated embodiment, the proximal attachment means 36 comprises a plurality of tines 40, inclined in the proximal direction and mounted to a sleeve 41 which extends the length of the catheter shaft 35. A first knob 42 is secured to the proximal end of sleeve 41, in proximity with a second knob 43 attached to the proximal end of an elongate shaft 44 which extends through sleeve 41. The interior surface of sleeve 41 may be provided with a female thread for engaging a male thread on the shaft 44, in the manner illustrated in FIG. 11, 35 illustrating an expansion catheter of the present invention. The important relationship is that the shaft 44 is capable of reciprocating movement within the sleeve 41, as will become apparent.

The distal attachment means 37 comprises a ring 45 which is rotatably attached near the distal end of shaft 44 by engaging an annular groove on said shaft 44 or other conventional means. A plurality of tines 46 are attached to the ring 45, said tines 46 radiating outward and inclined in a distal direction.

An outer sheath 47 is slidably mounted on the outside of sleeve 41. The interior lumen of sheath 47 is flared at the distal end 48 thereof so that the sheath 47 may be slid down over tines 40, causing them to resiliently bend radially inwardly yet remain inclined in the proximal direction. To help ensure that the tines 40 are not bent towards the distal direction by the sheath 47, the outer surface of tines 40 may be provided with a rounded edge 49. The mechanical features of the removal instrument will be made more clear by reference to the discussion of the method of removing an implanted stent, infra.

#### Expandable Tubular Stent

Referring to FIG. 4, there is illustrated a radially expandable tubular stent 18 according to the present invention, the stent being illustrated in its unexpanded, substantially cylindrical configuration and mounted on a balloon catheter. The wall thickness of the stent is advantageously from about 0.003 to about 0.06 inches, preferably is from about 0.005 to about 0.025 inches, and more preferably is from about 0.008 to about 0.012 inches. The wall of the stent is formed with a plurality

5 of passages therethrough, as best illustrated in FIGS. 6, 7 and 8, which depict wall patterns as they might appear if the wall of the stent 18 were rolled out flat. In FIG. 6, a first plurality of parallel filaments 50 are aligned at a diagonal to a second plurality of parallel filaments 51, all formed from a single piece of material to yield a diamond pattern having a plurality of diamond shaped openings 52 therethrough. This configuration of the filaments 50 and 51 permits radial outward deformation 10 of the tubular stent 18 in response to a radial outward force exerted by the expansion catheter 1 of the present invention. Construction of the stent from a malleable, biologically compatible metal such as titanium, or other materials discussed infra permits the stent 18 to hold its expanded configuration under stress exerted by, for example, a hypertrophied prostate gland, thereby maintaining patency in an otherwise stenotic or occluded lumen. In addition, orientation of filaments 50 and 51 is such that forces exerted upon the axial ends 38, 39 of an expanded tubular stent 18 in opposite axial directions will effect an axial elongation of the stent 18 and a consequent reduction in the diameter thereof.

15 A variation of the wall pattern of FIG. 6 is illustrated in FIG. 8, wherein the roughly diamond shaped openings become smaller near the axial ends of the stent 18. This configuration facilitates greater expansion in the central region 64 thereof, and, like the pattern in FIG. 6, permits the expanded stent 18 to be reduced in diameter by applying an axially elongating force thereto.

20 The ratio of solid wall area to the total area of the opening therethrough is relatively low. This minimizes contact area between the material of the stent and the lining of the lumen, may improve the expansion characteristics of the stent, and minimizes interference with vessels entering the urethral lumen from the side, such as the prostatic ducts, and the terminal portion of the ductus deferens, which traverses the prostate to empty into the urethra. In addition, the transverse openings through the wall of the stent may promote tissue ingrowth thereby minimizing encrustation of the filament portions 50 and 51, of the stent by dissolved minerals, and reducing the risk of migration of the stent in the direction of the bladder.

25 Optimally, the wall thickness of any given stent will be substantially uniform throughout, however, in one embodiment of the present invention, the wall is thinner in the central region 64. The thickness of the stent wall as measured in the radial direction may be different in different stents in order to permit a greater or lesser area of transverse openings therethrough, while maintaining structural integrity of the stent. It is important that the stent 18 be capable of withstanding the constant radially inward directed force exerted by a hypertrophied prostate gland.

30 The axial length of the stent 18 should be sufficient that pressure exerted by the hypertrophied prostate cannot cause stenosis of the lumen beyond the axial ends thereof. The length of the stent will often be from about 1 cm to about 4 cm, depending upon the location and extent of the hypertrophy or hyperplasia, is preferably from about 1.5 to about 3.0 cm in length and most preferably is about 2.4 cm in length, which is the average approximate length of the prostatic urethra.

35 Preferably the stent of the present invention will be made using a biocompatible material, either throughout, or in the form of a coating over the stent, which will improve its compatibility with the physiological and chemical environment within the urethral lumen. For

example, the stent will be exposed to urine having a pH in the range of from about 4.5 to 8, a relatively wide variation compared to other body fluids such as blood, which generally has a pH of about 7.4. The coating may be a plastic or polymeric material, such as a fluoropolymer, for example polytetrafluoroethylene, or preferably silicone rubber. Alternatively, the coating may be isotropic carbon, and the surface of the stent may be either smooth or microporous in nature. It is believed that a smooth surface is desirable because irregularities in the surface may provide sites for precipitation of salts due to the relatively high osmolality of urine. A sufficiently smooth surface would thus minimize encrustation of the stent. A surfactant or chelating agent may advantageously be affixed to the surface of the stent, for further reducing encrustation thereof.

The maximum expanded diameter of the stent 18 will likely be within the range of from about 10 mm to about 14 mm or greater. This range refers to the largest cross-sectional dimension in the case of stents which are enlarged to a configuration having a non-circular cross section or a non-cylindrical profile. Depending upon its construction material and physical design, a given stent may be expanded within an optimal range, which may be less than the overall ranges indicated above.

The stent 18 of the present invention may be expanded from a first, unexpanded configuration to a second, expanded state having a substantially uniform cross section throughout the axial length thereof, or to a configuration having a greater cross-sectional area in the central region than in the regions near the axial ends thereof. This latter configuration is achieved, for example, by a mechanical design of the stent 18 which permits greater expansion in the central region, such as by slotting with greater frequency in the case of a malleable metal stent, or by choice of a material for the central region of the stent having greater expansion abilities than a different material incorporated into the axial end regions 38 and 39. For example, the sidewall pattern illustrated in FIG. 8 would permit greater radial expansion near the center than at the axial ends. Alternatively, graduated wall thicknesses on a stent of uniform composition could be employed. Preferably, however, the configuration of the expanded stent 18 corresponds to the expanded shape of the balloon 8 used to accomplish its expansion. Thus, the catheter 1 of the present invention may be provided with balloons 8 having a variety of fully inflated profiles, for example, cylindrical, concave, convex, or frusto-conical, to suit any of a variety of clinical indications. FIGS. 15 and 18, for example, illustrates a stent that has been expanded by a balloon having a convex profile.

In the embodiment illustrated in FIGS. 15 and 18, migration of the stent 18 is minimized due to the restrictive forces caused by the normal tissue in the area of the bladder neck. The enlarged midsection 64 of the stent 18 would be unable to pass through the restricted neck of the bladder because any forces tending to cause migration would generally be insufficient to force a stent of this configuration axially through the urethra. For similar reasons, migration of the stent away from the bladder would also be minimized.

In addition, the stent is advantageously expanded to have an oval or otherwise non-circular cross-sectional area, such as that illustrated in FIG. 7. The stent is advantageously expanded to have a configuration which closely approximates the cross-sectional shape of

the native prostatic urethra, and may permit normal contractions of the prostate gland.

According to another embodiment of the stent 18 of the present invention, the axial end regions 38, 39 of the stent 18 are softer or more flexible than the region in the center of the stent 18 thereby allowing a smooth transition from the lumen 19 of the stent 18 to the lumen of the urethra. The axial end regions 38, 39 of the stent may be formed with a gradual taper in a radial inward direction, thereby reducing the risk of stress and irritation, and possibly even kinking of the urethral lining at the graft-urethra lumen juncture.

Referring to FIG. 16, there is illustrated in simplified form a sectional view of the male pelvic region, showing the bladder 59, an enlarged or hypertrophied prostate gland 60 causing a stenosis 61 of the prostatic urethra 62. Thus, the interior diameter of the prostatic urethra 62 has become smaller than the interior diameter of the non-prostatic urethra 63.

Referring next to FIG. 17, there is illustrated an expanded stent 18 within the prostatic urethra 62, having a substantially uniform cross section throughout the midsection 64 thereof, and a radially inwardly directed taper near the axial ends 38 and 39. The expanded state diameter of the stent 18 is slightly exaggerated for illustration. Referring to FIG. 18, there is illustrated an expanded stent 18 in position within the prostatic urethra 62, having a generally convex exterior configuration throughout its axial length. In this latter preferred inflated state configuration, the resilient force exerted by the prostate gland 60 acts in cooperation with the generally convex stent 18 to minimize the likelihood of migration of stent 18 into the interior of bladder 59, or into the urethra 63 downstream of the prostatic urethra 62.

A malleable metal stent according to the present invention, comprising, for example, titanium, may be manufactured by first machining titanium tube or sheet stock to the desired wall thickness, generally in the range of from about 0.004 to about 0.05 inches, and then cutting or etching the wall pattern thereon, such as one of those patterns illustrated in FIGS. 6, or 8. The cutting may advantageously be accomplished using a laser system, such as a Koppers Laser System marketed by the Laser Systems Division of Koppers Company, Inc., of Westminster, Md. Tube stock may be laser cut on a revolving mandrel, whereas sheetstock may be laser cut in sheet form and subsequently rolled into tubular form, welded, and polished.

#### Method of Placement and Dilation of Expandable Tubular Stent

In accordance with the insertion method of the present invention, a dilation means 1 having a suitable expandable stent 18 associated therewith is selected and then transurethrally positioned within the prostatic urethra 62 by way of the external opening 65 of the urethra 63. The positioning step may advantageously be accompanied by or preceded by the introduction of a radiopaque dye through dye port 14, from which it will be conducted via lumen 12 through the catheter 1 to the area of stenosis 61, to enable visualization thereof. The positioning step may also advantageously be preceded by coating the catheter 1 and stent 18 disposed thereon with a water soluble surgical jelly or other lubricant, such as Surgilube®, a sterile, bacterio-static surgical lubricant, available from E. Fougera & Co., Melville, N.Y. Positioning may also be accomplished with the use

of a guidewire 13, in accordance with known catheterization techniques.

With the balloon catheter 1 in position, a pressurized fluid is introduced into inflation port 3 which, by way of lumen 5 and inflation duct 9 enters the balloon 8. Vent port 4 may be vented until all air has been purged, at which time it is sealed by closing a stopcock or other conventional means. Inflation of the balloon 8 causes radial expansion of the expandable stent 18 and also dilation of the surrounding lumen against the pressure exerted by the hypertrophied prostate gland 60. The radially expandable stent 18 is advantageously dilated sufficiently that the inside diameter of the lumen 19 therethrough exceeds the outer diameter of the region of the catheter between the annular depression 15 adapted to receive the undilated stent 18 and the distal tip 20 of the catheter 1, so that the catheter 1 may be withdrawn through the lumen 19 of the expanded stent 18 leaving said stent 18 in place within the prostatic urethra.

By varying the configuration of the balloon 8 in the case of a balloon catheter, as previously discussed, the stent 18 may be expanded to a final shape having a substantially circular cross section, or a cross section that more closely adheres to the natural configuration of the normal lumen inside the urethra.

Following dilation of the intraluminal stent 18, the dilating catheter 1 may be reduced in diameter by exhausting the pressurizing fluid under any contractile force of the balloon 8 and then evacuating the contents of the balloon 8 by way of inflation port 3. The apparatus may then be withdrawn through the lumen 19 of stent 18, leaving the expanded stent 18 in place within the prostatic urethra 62, illustrated in FIGS. 17 and 18.

#### Method for Subsequent Dilation of Expandable Tubular Stent

The apparatus 1 may at a later time be reinserted, via the external opening 65 of the urethra 63, should it become necessary to further increase the diameter of 40 the stent 18 within urethral lumen 62 or to redilate the expandable stent 18. According to this aspect of the process of the present invention, a previously positioned and dilated stent 18 is fluoroscopically visualized in accordance with known techniques. An appropriate 45 catheter 1 having a balloon 8 with the desired inflated state configuration is selected, transurethrally inserted as discussed supra, and positioned with the deflated balloon 8 coaxially disposed within the prepositioned, expanded stent 18. For this purpose, the catheter 1 may 50 be provided with one or more radiopaque markers 66 for visualization of the location of the balloon 8. The balloon 8 is then inflated, re-expanding, further expanding, or altering the configuration of the stent 18. Thereafter, the balloon 8 may be deflated, and the catheter 1 55 is withdrawn, leaving the re-expanded stent 18 within the prostatic urethra 62.

#### Method for Removal of Expanded Tubular Stent

In yet a further aspect of the process of the present invention, a prepositioned stent 18 may be removed through the use of a removal instrument equipped such as that illustrated in FIG. 12 with attachment means 36 and 37, described supra, and adapted for insertion through the operating channel of a urethroscope or cystoscope. The urethroscope is transurethrally inserted, by way of the external opening 65 of the urethra 63, and positioned such that the previously positioned

stent 18 may be directly visually observed. Under direct observation, the removal instrument is positioned coaxially within the prepositioned stent 18 by way of the operating channel of the urethroscope. During this positioning step, the sheath 47 is slid axially in a distal direction to cover distal attachment means 37. When both attachment means 36 and 37 are positioned within the lumen 19 of an expanded stent 18, the sheath 47 is axially retracted, exposing said attachment means 36 and 37. The tines 40 and 46 resiliently bend in a radial outward direction in the absence of sheath 47, until they reach approximately a diagonal as illustrated in FIG. 13. As shaft 44 is axially extended, e.g. by rotating knob 43 while knob 42 is held stationary, the proximal tines 40 will engage the proximal end 38 of the stent 18 by extending through the openings 52 or 58 illustrated in FIGS. 6 and 7. In a similar manner, the distal attachment means 37 is caused to engage the distal end 39 of the stent 18. The attachment means are thereafter moved further apart in an axial direction, causing an axial elongation of the implanted stent 18. Due to the configuration of the side wall of the stent 18, a reduction in the radius of the stent 18 results. Once sufficiently reduced in diameter, the sheath 47 is slid distally to cover both attachment means 36 and 37, having the radially reduced stent 18 attached therebetween. The urethroscope and the removal instrument, having the elongated stent 18 still engaged, may thereafter be transurethrally withdrawn.

Although this invention has been described in terms of certain preferred embodiments, other embodiments that are apparent to those of ordinary skill in the art are also within the scope of the invention. Accordingly, the scope of the invention is intended to be defined only by reference to the appended claims.

What is claimed is:

1. A method for treating hypertrophy of the prostate gland, comprising the steps of:  
positioning a dilation means having an expandable tubular stent associated therewith within the prostatic urethra; said dilation means comprising a catheter having a circumferential recess thereon in which an expandable balloon is mounted, wherein said stent is positioned over said balloon in said recess, and wherein said positioning step includes protecting the urethral lining from damage by minimizing sliding contact with said stent by maintaining said stent in said recess during said positioning; dilating the expandable tubular stent with said dilation means to deform said stent, to expand the prostatic urethra, and to maintain such expansion against radial inward forces generated by said prostate; restoring said dilation means to its substantially unexpanded state; and removing said dilation means and leaving the dilated tubular stent within the urethra.
2. A method as in claim 1, wherein said positioning step comprises the transluminal insertion of said dilation means, by way of the external opening of the urethra, without the use of a sheath.
3. A method as in claim 1, further comprising the step of introducing a radiopaque dye for fluoroscopic visualization.
4. A method as in claim 1, further comprising the initial step of selecting a balloon catheter having an expanded configuration of the balloon corresponding to

the interior configuration of the native prostatic urethra, prior to stenosis by prostatic hypertrophy.

5. A method as in claim 1, wherein said stent comprises a biologically inert material.

6. A method as in claim 1, wherein the radial dilation of said stent results in a substantially uniform cross-sectional area along its axial length.

7. A method as in claim 1, wherein said stent is outwardly radially expanded to a greater final cross-sectional area in a central region than at the axial ends thereof.

8. A method as in claim 7, wherein said stent in its expanded state comprises a non-circular cross section.

9. A method as in claim 2, further comprising an initial step of inserting a guidewire prior to the transmural insertion of said dilation means.

10. The method of claim 1, wherein the diameter of said catheter on either side of said recess is at least about as great as the unexpanded diameter of said stent.

11. The method of claim 10, wherein said catheter and said unexpanded stent mounted thereon together form a substantially cylindrical configuration.

12. A method as in claim 1, further comprising the steps prior to said positioning step of:

providing a plurality of balloon catheters having 25 different expanded configurations, and selecting said dilation means from among said balloon catheters.

13. The method of claim 12, further comprising the steps after said removing step of repeating the providing, selecting, positioning, dilating, restoring and removing steps of claim 39, wherein the balloon catheter selected in said repeated steps has a different expanded configuration than the balloon catheter first selected.

14. An apparatus for relieving the symptoms of prostatic hypertrophy, comprising:

an axially elongate catheter shaft having a proximal and a distal end of a size suitable to be inserted in a human urethra; an inflation port at the proximal end of said catheter 40 shaft, in fluid communication with a radially expandable balloon disposed near the distal end of said catheter shaft by means of a first lumen extending axially therethrough; a vent port at the proximal end of said catheter shaft 45 in fluid communication with said expandable balloon by means of a second lumen extending axially through said catheter shaft; a removably mounted, radially outwardly expandable tubular supportive stent coaxially disposed about 50 the expandable balloon, said stent being formed from a malleable material which is biologically compatible with a urethra and comprising an opening at each end and a central lumen therethrough; wherein said stent is radially deformable from a first 55 unexpanded state to a second, expanded deformed state in response to pressure from said balloon and is capable of withstanding said expanded, deformed configuration against inward forces exerted from a hypertrophied prostate; and the outer diameter of the stent in its first, unexpanded state is not substantially greater than the outer diameter of the adjacent catheter shaft, the catheter shaft and stent mounted thereon thereby having a substantially uniform cylindrical profile such that 60 the apparatus may be transurethrally positioned within the prostatic urethra by way of the external opening of the urethra with said stent substantially

totally exposed to the wall of the urethra, without the use of a sheath, and with said stent substantially totally exposed to the wall of the urethra.

15. An apparatus for relieving the symptoms of hypertrophy of the prostate gland, comprising:

an axially elongate catheter shaft; an expandable region on said shaft disposed near the distal end of said shaft; a removably mounted, radially outwardly expandable tubular stent disposed on top of said expandable region and adapted for insertion into the prostatic urethra; and

means on said catheter shaft for protecting the urethral lining from damage due to sliding contact with said stent, said protecting means comprising at least one circumferential shoulder on said catheter abutting said stent and said expandable region, the diameter of said shoulder being at least as great as the diameter of said stent so that said stent does not extend radially beyond said shoulder, wherein said stent is radially expandable by deformation thereof to a preselected stable configuration in response to pressure from said expandable region on said shaft.

16. An apparatus for relieving the symptoms of hypertrophy of the prostate gland, comprising:

an axially elongate catheter shaft comprising at least one lumen therethrough and having an annular recess thereon for receiving a stent; an expandable balloon mounted on said shaft in said recess and in communication with said lumen; and a removably mounted, radially outwardly deformable and expandable tubular stent coaxially disposed about said balloon and situated in said recess, wherein said stent has an opening at each axial end and a central lumen therethrough,

wherein said stent is radially expandable by deformation to a preselected configuration in response to pressure from said balloon, and the outside diameter of the stent, in its unexpanded state, is not substantially greater than the outside diameter of the adjacent catheter shaft.

17. An apparatus for relieving symptoms of hypertrophy of the prostate gland, comprising:

an axially elongate catheter shaft having at least one lumen therethrough and having a circumferential recess near one end thereof;

an expandable balloon mounted on said shaft in said recess and in communication with said lumen; a removably-mounted, radially outwardly expandable tubular stent coaxially disposed about said balloon, said stent having an opening at each end and a central lumen therethrough;

wherein said stent is radially expandable by deformation thereof to a preselected configuration in response to pressure from said balloon, and wherein the outside diameter of the stent, in its unexpanded state, is not substantially greater than the outside diameter of the adjacent catheter.

18. An apparatus as in claim 17, wherein said balloon in its expanded state, has a non-cylindrical configuration.

19. An apparatus as in claim 17, wherein said balloon in its expanded state has a non-circular cross section along its axial length.

20. An apparatus as in claim 17, wherein said balloon in its expanded state has a smaller cross-sectional area at its axial ends than in the central region thereof.

21. An apparatus as in claim 17, wherein the expanded cross-sectional area of said stent is unresponsive to the radial inward pressure responsible for the stenosis of the urethra.

22. An apparatus as in claim 17, wherein said catheter further comprises a lumen for receiving a steerable guidewire therethrough.

23. An apparatus as in claim 17, further comprising at least one radiopaque marker associated with the axial position of said balloon.

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24. An apparatus as in claim 17, wherein said balloon expands to a configuration having a non-circular cross section, and a convex profile along its axial length.

25. An apparatus as in claim 17, further comprising a biocompatible, essentially smooth coating on said stent.

26. An apparatus as in claim 25, wherein said coating comprises silicone rubber.

27. An apparatus as in claim 17, wherein said stent further comprises a flexible, resilient region at each axial end thereof.

28. An apparatus as in claim 17, further comprising a lubricant coating around said tubular stent.

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